00331279   **Image available**
PRESCRIPTION MANAGEMENT SYSTEM
SYSTEME DE GESTION DES PRESCRIPTIONS
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English Abstract
 A wirelessly deployable, condition-oriented, electronic prescription
 management system (figure 16) for physician use which provides for
 patient record assembly (10) with privacy controls (39) for patient and
 doctor, adverse indication review (42), online access to comprehensive
 drug information (50) including scientific literature, extensions to
 novel multi-drug packages and dispensing devices, and an "intelligent
 network" remote data retrieval architecture (figure 16). Onscreen
 physician-to-physician e-mail is also provided.

French Abstract
 Systeme electronique de gestion (fig 16) par radio des prescriptions
 fonction de l'etat des malades destine a un medecin, regroupant les
 dossiers des patients (10), garantissant la confidentialite (39) et
 fournissant: une liste des contre-indications, des informations completes
 en direct sur les medicaments (50) et la litterature scientifique, des
 annexes sur les nouvelles associations de medicaments, des systemes
 d'administration et un "reseau intelligent" de recherche a distance
 d'informations (fig 16). Est egalement prevu un echange d'informations
 entre medecins par courrier electronique.

Detailed Description

PCTIUS95/14118 PRESCRIPTION MANAGEMENT SYSTEM
TECHNICAL FIELD
This invention relates to professional data management systems useful in
the production of product specification documents such as prescriptions,
service or parts orders, insurance contracts and the like that require
detailed product ax-id history information from multiple extensive inform
ation sources, especially remote heterogenous sources. More particularly,
the invention relates to systems that assist professionals perform their
everyday work in-specifying customized technical products. A particularly
preferred embodiment relates to a computer-implemented prescription
management system to assist physicians in prescribing and reviewing
drugs.

BACKGROUND
An important professional activity undertaken by most physicians during
the course of their day is the prescribing of drugs. Many physicians
prescribe a great number of drugs every day. Studies show that over two
thirds of all doctor-patient encounters 5 were completed with the writing
of a prescription . In 1993 typical prescribers were prescribing in
excess of two hundred thousand dollars-worth of drugs annually.

While most physicians exercise the utmost of professional skill and
caution in prescribing, there are inherent difficulties and uncertainties
in the process. Most physicians will probably agree that they do not have
access to adequate, reliable drug information and relevant patient
infon-nation at the time and point of prescription .

In particular, information regarding relevant new drugs, comparative
efficacy, and importantly, relative costs, may not be readily and
conveniently available to a physician creating a new prescription , as
well as relevant patient information such as current conditions being
treated, current treatments, and preferred medications for conditions,
pursuant to requirements of the patient's drug formulary.

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Nevertheless, while accessing it is impractical for the typical
practitioner, such information is available to any physician willin to
take the time and make the effort
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to obtain it.

In contrast, integrated patient-specific information which is directly
relevant to treatment management for the subject patient is frequently
both unavailable to, and unobtainable by, a prescribing physician unless
that physician's institution or organization has been exhaustively
responsible for the subject patient's prior care and maintains

sophisticated computerized records. Information as to allergies, current prescriptions and currently active conditions is clearly desirable or essential for intelligent prescribing. In 1994, few prescribing sessions are conducted with the benefits of integrated patient-specific information and fewer still have the benefit of specific drug formulary recommendations on the subject patient.

Typically, drug formularies comprise lists of preferred drugs whose costs will be borne by a drugs benefit house. Drug formulary information is usually determinative of the cost-effectiveness of a prescription . Unwitting failure by a prescriber to follow formulary guidelines can impose unnecessary or unexpected cost burdens on the patient, or their benefits provider, and lead to poor patient compliance and aggravating and time-consuming disputes. TI-ie cost in dollars of non-compliance with drug formulary guidelines to benefit-providing corporations, insurers, health maintenance organizations and government providers, for example MEDICAID and MEDICARE, can be enormous. The cost of poor patient compliance may ultimately increase the total cost of care by generating a more serious, expensive adverse health outcome (emergency room visit, or hospital admission or death).
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A difficulty in making integrated patient-specific infori-nation readily available to prescribing professionals is that the needed information components are not centralized but are widely distributed geographically and even when their geographic or electronic locations are known, are hard to access because of proprietary and liability and patient-confidentiality concerns and because of system, file or protocol incompatibilities.

Even in the computer-abundant United States, in the mid-90's, prescription writing is generally a manual process. After consulting with a patient to deten-nine their problems and diagnosing, or attempting to diagnose their condition or disease, a physician selects a drug and a dosage and an amount to prescribe based upon their own personal knowledge and experience, if necessary using available reference materials which may or may not include promotional materials from drug manufacturers. A prescription is then written up under the physician's signature and bears a patient identification, a drug name, dosage amount and timing, refillability information and the physician's signature, the date, possibly an advisory regarding contraindications, and little other information. While a prescription may be typed, 30 keyed or otherwise "generated" on a computer most prescriptions are still manually written. Prescribing activity should be a good field for computerization, but one difficulty is the lack of apparent benefits to many physicians. Paper prescription pads are small and easily carried around by a physician. Manually writing a prescription will often be quicker and easier than

using a computer, however good the system. The benefits of automated information svstems often come not from greater data entry efficiency, but from the increased efficiency of the entire process, from the value of the transaction records generated and also from the control of the transaction entry I 0 process which may ensue. Physicians who are not computer-literate or who are even "computer-phobic" will require a most compelling reason to adopt a computerized prescription management svstem.

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To be fully effective, a prescription management system must be readily usable by a wide range of physicians, preferably for all their prescribing activity must provide compelling value to patient care and increase overall treatment management efficiency. Providing an attractive computer-based system to physicians is fraught with unexpected difficulties.

Physicians and other health care professionals, especially those with prescribing authority, are representative of certain groups of professionals whose unique characteristics raise obstacles to the computerization of their day-to-day professional activities. Desirably, a computerized professional management system should be capable of flexible integration into their personalized and varied work flows.

Contrary to many perceptions and assumptions in conventional data-management systems intended for use by physicians, clinicalphysicians are not deskbound WO 96/13790 PCTfUS95/14118 from hospital to hospital and to and from their car and home. While some physicians may spend the majority of their health care patient encounter activities at or near a desktop in their own office, such physicians are probably the exception. In clinics and hospitals physicians are often continually on the move between 5 examination rooms, reception areas, administrative centers, hospital wards, specialist facilities such as radiology rooms ahd so on and so forth. In addition many physicians have more than one practice or more than one professional activity which takes them between an office or clinic and a hospital or other facility on a regular basis. Accordingly, it is a significant technical challenge to provide such mobile I 0 physicians with access to a computer-implemented management system that is readily available at the point of care.
Portable computers are a possible solution to the access problem now that powerful and compact notebook computers are widely available. Although currently available portable computers offer some advantages particularly to physicians moving between one work place and another, they also suffer certain drawbacks. One drawback is that external communication is difficult being commonly effected bv moving diskettes, a valuable but limited method, or by modem connection to a telephone line which

inconveniently requires plugging into a wall jack. Though possibly adequate for a physician having multiple offices, neither the communication means nor the portability of such systems is satisfactory for a ward physician moving from patient bed to patient bed. The weights and fon-n factors of traditional portable computers are severe impediments to their assimilation into many clinical physicians daily lives as dependable assistants to their professional work.

More recently, small handheld or palm computers known as personal digital assistants or personal infon-nation communicators have become available. An example is the Apple NEWTON trademar1c). As of summer 1994, these ate rather rudimentary devices as compared with desktop or full-powered portable systems, having modest permanent and RAM storage capacities and limited processing and communications abilities. Attractive to busy mobile professionals for their small size,
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such handheld computers can also embody highly desirable radio wave or infrared wireless communications abilities enabling them to exchange data with host systems without the cost or inconvenience of hard wiring.

uch portable hand held radio communicating computing devices are attractive for computerizing mobile professionais such as physicians, but their processing and storage limitations represent a real problem in providing a sophisticated, capable and attractive system for physicians.

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A broad objective of this invention is to provide a prescription management system that can be used by physicians on such mobile computing devices.

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imply delivering a system on a convenient portable computer will not be enough to assure its regular use by a majority of physicians. Though highly educated and technical1v skilled, many physicians are not computer literate and are averse to confronting a computer screen. ome mav even be intimidated by computers. Nor do their busy schedules permit time to learn complex or difficult systems. Even for an experienced user adoption of computer use into their daily routines requires time change and adaptation. With tremendous competition for their time, physicians will only be willing to take these steps if they are enticed by powerful system features that provides them with compelling value to patient care and overall practice management efficiency.

Nevertheless, the greatest of system features will be worthless if the system hinders the professional in executing routine functions. Even at sophisticated computer products companies with access to, and experience

with, state-of-the-art systems, telephone sales staff often take down orders with pen and pad rather than using an on-line sales order svstems.

An experienced professional practicing their specialty for example a pediatrician treating infants knows from experience exactly what to prescribe, in many instances.

They will have neither the time nor the patience to work their way through conventional software selection and data entry procedures. Accordingly, a further 5 object of this invention is to provide a prescription management system which personalizes itself to the prescribing patterns of experienced users.

SUMMARY OF THE INVENTION

This invention solves a problem. It solves the problem of providing a computerized, prescription management system that an average prescribing physician can use and will want to use and which makes possible significant improvements in the quality of prescriptions written. In preferred embodiments, the invention also solves the problem of significantly reducing prescription costs to patients and to their drugs benefit management company or government agency.

The invention solves these problems for physicians by providing a prescription management system for electronic prescription creation by a prescriber at a point of patient care, said prescription being usable by a pharmacist to dispense drugs, said prescription management system comprising.

a) electronic posting means to select and capture in said prescription .

i) a patient identifier;
ii) a prescribed drug;
iii) a dosage for said prescribed drug; and
b) a patient-condition treatment specification procedure;
whereby in creating said prescription said prescriber specifies a patient condition for treatment by said prescribed drug.

More generally, the invention provides a computer-based professional product specification system for use by other professionals, in addition to physicians, which
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can deliver substantial benefits to mobile, users who may be computer-inexperienced.

By associating a patient condition or problem with each drug prescribed, a treatment objective is both expressed and recorded .... phvsician intent... and deliver for physicians the problem is solved by providing a

user- friendly prescription management system, requiring minimal data entry enabling prescriptions to be 5 created with an overall efficiency unobtainable by any known automated system and which can helpfully supplement the'skills of the best of practitioners.

Pursuant to one preferred embodiment of the invention, the drugs in the drug list are classified according to a patient condition for which the drugs are effective and the onscreen drug selection procedure lists multiple drugs for treating each patient - problem. In an alternative embodiment, the user makes a drug selection by generic or brand name or some other drug identifier, and the system supplies, suggests or requires, entry of an appropriate treatment condition so that the patient record is completed with the condition or conditions for which the selected drug is prescribed.

The invention also provides a user-adaptive prescription management system for electronic prescription creation by a prescriber at a point of patient care, said prescription being usable by a pharmacist to dispense drugs, said prescription management system comprising.

a) electronic posting means to select and capture in said prescription .

i) a patient identifier;
ii) a prescribed drug;
iii) a dosage for said prescribed drug;
b)' a patient-condition treatment specification procedure wherebV in creating said prescription said prescriber specifies a patient condition for treatment by said
prescribed drug;
c) an onscreen drug selection procedure having a patient condition list specifying multiple possible patient conditions, having a drug list specifying multiple possible prescribable drugs and having drug specification means to select and
post a desired drug to said prescription ; and
d) tracking means to track preferred data usage by a user and to adapt data displays to favor such preferred usage, whereby the system learns and adapts
to a user's habits;
wherein drugs in said drug list are classified according to a patient condition for which said drugs have efficacy and said onscreen drug selection procedure lists multiple drugs for treating each said patient problem.

Drug lists or individual drug selections or suggestions may be presented to prescriberusers in any of a varietv of ways for example by frequency of prescription for a I 0 selected condition, based upon either the

user's historical prescription activity or a wider base of historical prescribing activity, which could be nationally or regionally defined or derived from a drugs benefit house, health maintenance organization, hospital or other appropriate institution.

1 5 ystem suggestions for condition-related drug selection may be further refined into categories such as relative cost, generic or brand name and so on. Where many drugs are available for treating a patient's active condition, one particularly useful presentation is by multiple lines of therapeutic preference according to drug formulary guidelines. Thus, within the patient's particular formulary there may be suggested first, second and third lines of therapy. Different suggestions may be made for different patients according to the preferences of the patient's particular drugs benefit management company.

Preferably the system includes a comprehensive database of approved drugs classified by conditions for which they are known to have therapeutic effect and this database need not be maintained in the users station but should be accessible in real time to the user. Many valuable professional benefits are obtained by delivering a selective listing of drugs by condition to a physician. For example in treating a particular chronic condition such as gastro-intestinal disease, a physician may find that common medicaments such as antacids are ineffective, that a particular brand name drug such as TAGAMET (trademark) has, with prolonged use, undesired side effects so that the physician may at this point be interested in gaining information about alternative drugs with which they are less familiar. If the physician does not have the information at their finger tips, this could be a time consuming process in their office reviewing Files and other archival information svstems they have. Alternatively online electronic services may be used but this can also be a time consuming process.

By offering a comprehensive selection of drugs known to be effective for a particular condition, this problem is easily solved for the physician. The preferred embodiments include back-up prescribing information on each drug, along with I 0 details of literature references supporting its inanufacturer's therapeutic claims or with means enabling the physician promptly to obtain such references.

The invention is not limited to providing a prescription management system. It can provide, in the medical Field alone, svstenis for clinical laboratory management, for 1 5 medical record management for radiology management and the like. In addition the invention can provide novel professional data management systems that can create new products and yield comparable benefits in other professional spheres where professionals are responsible for specifying more or less complex

technical products to solve client or customer problems.

In this wider aspect the invention provides a professional product specification system for electronically creating a technical specification usable by a professional to specify technical products said product specification svstem comprising.
a) electronic posting means to select and capture in said technical specification.

i) a customer identifier;
ii) a specified product; and
b) an onscreen product selection procedure having a product benefit list specifying multiple possible customer benefits having a product list specifying multiple possible specifiable products and having product specification means
to select and post a desired product to said specification;
wherein products in said product list are classified according to a customer benefit which said products can provide and sa-,i onscreen product selection procedure lists multiple products for providing each said customer benefit.

BRIEF DESCRIPTION OF THE DRAWINGS
By way of example, some preferred embodiments of the invention are described in detail below with reference to the accompanying drawings in which:
Figure I shows a svstem entry screen of a prescription management system embodiment of the invention which svstem incorporates the screens of Figures 2-1 1;
Figure 2 is a patient selection screen;
Figure 3 shows a prescription creation screen;
Figure 4 is a condition list selection screen,
Figure 5 is a condition selection screen;
Figure 6 is a drug selection screen, condition specified;
Figure 7 is a nonformulary drug selection screen;
Figure 8 is an alternative condition-specification and drug selection screen;
Figure 9 is an alternative direct drug specification screen;
Figure I 0 is a condition selection screen, drug specified;
Figure I I is a drug selection evaluation screen;
Figure 1 2 is a single prescription history screen.

Figure 1 3 is a patient problem history infon-nation screen; and
Figure 1 4 is a manually updatable problem list maintenance screen;
Figure 1 5 illustrates a scheduled dosage drug package; and
Figure 1 6 is a schematic diagram of one way of connecting users of the prescription management system of Figures I- 1 4 with remote

source databases across network to provide data and processing resources needed during operation of the prescription management system and useful inter alia for creation of a virtual patient record.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Overview

The prescription management system illustrated in Figures I- 14 can be provided in software for single-user operation on a stand-alone personal computer for use, for example, by a sole practitioner or for multi-user operation on a local area network for use, for example, by physicians and other prescribers within a single facility, hospital, group practice, or the like prescribing organization, and the invention can bring substantial benefits to such users and their patients.

However, more significant benefits can accrue to patients, physicians, drug benefit providers and the public at large by implementation of the described prescription management system on a regional or nation-wide basis. To this end, a preferred embodiment of prescription management sVstem comprises a host computer facility supporting wired or wireless network delivery of user-relevant components of said prescription management system to multiple remote user interface devices.

The host computer facility provides data, or access to data, data processing and communications resources for users to draw upon via the user interface devices. The host computer facility can be a server or cluster of servers with associated data storage volumes, and at least one intelligent client providing access to the server or servers. As will be explained in more detail hereinafter, especially with reference to Figure 16, the host computer facility can call upon a varietv of external resources and functions as a marshalling and processing center for organizing resources into useful and manageable pieces for utilization by limited capacity user-interface devices. In a preferred embodiment it is a co-ordination point on a network for a number of userdevice clients. Preferably the network accesses or includes a number of remote database sources providing useful information elements to the system.

eferring to Figures I to 14 of the drawings, the screens shown employ user-friendly data selection and data entry devices such as are familiar to many computer users in Apple Corporation's Macintosh@ (trademark) and Microsoft Corporation's Windows operating systems, for example activatable buttons, pointers, scroll bars, icons, arrow 5 key, drop-down menus, windows and other screen symbols designed for actuation by a pointing device, for example, a mouse or trackball. More preferably, for compact "pocket-book" computer applications, the pointing device is a pen or stylus.

'nie prescription management system shown in this embodiment of the invention has
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been designed for implementation on physically compact, portable, user-interface devices such as small portable personal computers, especially hand held devices known as personal digital assistants. Those skilled in the art will understand that the system can readily be used on or adapted to other hardware platforms, for example, a physician's desktop computer and can be expressed in different software interfaces 5 from that shown, especially ones that use different input devices such as keyboards,
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touch pads or touch screens and the like.

Pursuant to certain user-adaptive aspects of this invention, the screens automatically personalize themselves, with use, to adopt the patterns and habits of a regular user of a particular device platform for the system, offering the user their most frequently used information, drugs, conditions, patients or patient groups, and so on as first line choices. This adaptive characteristic is a valuable benefit endearing the system to experienced users who may become impatient with hierarchically accessed data.

Ease of use and suitability of the system to keyless or minimally keyed platforms, especially PDA!s is promoted by minimizing the need for actual text or data entry by the user and by emphasizing instead data selection from extensive, preferably comprehensive, data lists. Preferred embodiments of the invention allow quick pen selection of data items through columnar pick lists.

The data lists, categories, groups, addresses or routes, can be organized in multiple hierarchies for rapid and flexible access to multiple large, remote databases, via multiple access routes to retrieve multiple related data elements and assemble them into a single data file, for example, a patient history file compiled from the data resources of a patient's historical health providers.

A desirable goal is to provide the physician-user with intelligent data lists that are, where possible, exhaustive and list, for example, all prescribable drugs, all conditions, all formularies or all patients and present tile physician with helpful first-line choices I 0 or defaults selected intelligently oil tile basis of historical data known to the system.

Preferablv, the selection means is fullv svsteni embodied, or automatic, operating transparently to the user and requiring a ininimum of

configurational or setup operations by the user.

1 5 Virtual Patient Record
An ability to compile what may be tenned a "virtual" patient record from
multiple remote databases of primary source information is a valuable
novel feature of preferred aspects of this invention. uch a virtual
patient record can be created in a chronologically current version by
online interrogation of all possible primary sources of electronically
recorded patient history elements, bv retrieving those elements and
assembling them into a complete record. Yet the record need neither be
drawn from,
nor committed to, permanent storage, obviating storage requirements for
accumulations of patient records.

The record can be assembled dynamically, on an as-needed basis, consulted
by an
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authorized system user, and then dissolved, without ever having been
saved, giving the record a virtual character.

ecord element retrieval and record assemblv are conducted under the
auspices of the host computer facilitv employing a novel patient data
directory service providing routing information to each patient's record
elements. For each patient, the patient data directory service lists all
institutions, including independent physicians, hospitals, HMO's,
insurance companies, and so on, known to have source historical records
on that patient, against a unique patient identifier, such as described
hereinbelow. Also listed are routing or address data enabling the host
facility to access institutional databases to retrieve record elements.
Access protocols detailing, for example, what data can be accessed, when
it mav be accessed, by whom or by what organization or department it may
be accessed, can be kept in a patientspecified directory, or elsewhere.

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Patients not listed in the directorv service can be searched at the
remote source databases and, optionally, at other, host computer
facilities supporting tile inventive system for other groups of users.

1 5 The complete, assembled patient history, or record, need never be
stored, unless the patient requests or consents to such storage, and it
serves some useful administrative or care-related function. torage or
archiving of a record that is potentiallv updatable from multiple
uncoordinated locations has the drawback of dating it. To become current,
the record must be refreshed from anv database containing a new data
element for that patient.

By using a dynamically assembled virtual record, and never storing it, potential problems of maintaining patient confidentiality and preventing unauthorized access to highly sensitive personal infon-nation can be mitigated or avoided. This aspect of the invention avoids proliferation of a patient's confidential history and permits primary source data proprietors to act as exclusive wardens of their individual confidential data elements.

Bio-12attern recoMition

Bio-pattern recognition of personal user characteristics including, for example, handwriting, signatures, voice patterns and fingerprints is an attractive medium for accepting user inputs, but in the present state of development of the technology, suffers drawbacks which disfavor use of bio-pattern recognition in preferred embodiments of the invention. Future developments such as greater processing capabilities in small user-interface devices, and more accurate and efficient bio.

pattern recognition techniques may change this picture and favor adoption of one or more forms of bio-pattern recognition.

Thus, handwriting recognition, is eschewed in preferred embodiments of the I 0 invention, at the present time, because writing is more tiresome to the user than pointing, pressing or clicking and adds complexity and processing overhead to the svstem. Additionally, handwriting recognition, although presently available in pioneer systems, adds uncertainties, may require significant user effort or adaptation and mav threaten data accuracy or promote user error.

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ignature recognition mav be desirable, if permitted by regulatory agencies, for remote electronic authorization of fulfillment at tile pharmacy especially for mail order prescription fulfillment and the phannacy-prescriber link call, if desired, add additional levels of securitv bv transmitting or exchanging supplemental electronic identifiers.

However, better security, in terms of ensuring that the filled prescription is released to the intended patient, or their agent, may by provided, by treating an electronic prescription transmission to a pharmacy as an advisory against which fulfillment may be initiated, while the prescription is released only in exchange for a manually signed hard (paper) copy. ignature recognition or transmission as all individual graphic element, insofar as it may be useful or required in the prescribing process, can accordingly be incorporated in systems according to the invention. Processing demands on the user's device can be minimized by confining the device's capabilities to recognition of the signatures of only those users authorized to use that particular device.

Adding higher performance hardware to support the processing needs of handwriting recognition may be impossible with available technology if a preferred lightweight, compact form factor is to be retained for the user's device. An aim of the invention is to provide a qualified prescribing professional with a valuable tool that imposes no significant burdens of weight or volume on the user, that demands little of their time and yet can respond rapidly, delivering valuable drug and patient information to the user from remotely located, disparate sources. In other words, an aim of the I 0 invention is to provide an intelligent, knowledgeable computerized prescription pad.

This aim could be compromised by adoption of handwriting recognition technology at the date of this application. imilar problems apply to voice recognition as a significant data input medium. Either or both handwriting and voice recognition 1 5 may be valuable enhancements of future embodiments of the inventive systems especially if future technology makes these capabilities available on smaller user devices. In particular, limited voice recognition may be valuable as a user identifier for password access or as an authorizing signature.

Securi
ecurity may be provided by password protection operating hierarchically on one or more levels, to provide varying degrees of access according to the user's level of authorization, as desired. Additional password or numeric code control may protect sensitive svstem-accessed information, for example, patient records, or parts thereof, or physician-user data, including personal lists and prescribing profiles.

Patient record access codes can, in selected instances, be patient provided, or granted by intelligent security control cards, having been furnished to the patient by a system
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administrator, or agent, prior to the physician encounter. Physician or other user 30 access to a patient's record, or to sensitive details thereof, can therebv be restricted to a need-to-know basis. Access by third parties to physician-related data can be similarly protected.

Provision for override of such security features should be available, for example for an emergency room doctor, and is allowed on a special case exception basis, is auditable, and traceable to the overriding user.

Password-controlled access to many computer networks is often workstation dependent with each workstation using a unique password to access the network.

I 0 Although user passwords may also be employed, these are often woricstationdependent, for example, being incorporated in the woricstation's login scripts. In contrast thereto the present invention prefers that user access to tile host computer facility be device-independent so that a given user can access tile system via any of numerous devices, provided they have the right password or passwords. By this means, users are not dependent upon a single device that may be lost or misplaced.

A still more preferred feature is to have user passwords which link each user with an individual profile or style sheet on the host computer facility representing the user's patterns of preferences so that the User-customization features of the system, which will be described more fully hereinafter, are readily available to the user independently of the particular interface device that happens to be employed for accessing the system.

These and other device-independent features can permit the prescription management system to be fully operative without committing useful data to storage on the user device. This is a valuable security feature. In the event of theft or attempts at unauthorized use, even by skilled third parties, a user device will be WO 96/13790 PCTfUS95/14118 software, after user notification, by erasing or otherwise rendering device-resident application procedures inoperable, without loss of device-resident data. Use of a virtual patient record, as described herein, which need not be stored locally, is a valuable safeguard against unauthorized access of confidential data on lost, stolen or "borrowed" user devices.

Host computer facili1y
Currently contemplated preferred embodiments further control the processing and storage demands placed on the user's device by intelli ently delegating data
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processing and storage activities to a linked remote, host computer facility, as referenced above, to the extent warranted by the capabilities of the user device.
Thus, for example, a comprehensive drug database may be stored and maintained on such a host computer facility with selected data, for a particular drug list or an individual drug's formulation characteristics, being forwarded to the user's device on 1 5 an as-needed basis, then being eliminated from the user device when no longer required. Other activities may advantageously be performed locally on the device, such as dynamic assembly of records from elements retrieved across the network from remote storage, and storage of the user's personal or most frequently referenced data and data lists, where the device's capabilities permit.

Where the user device is more powerful than present-day PDA's, for example a present-day desktop computer or perhaps the PDA's of the future, more processing and data storage functions can be retained at the user device rather than delegated to the network. Althou h permanent (disk, diskette or flash memory) storage may have
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uses, security concerns can be better managed on the network than on the user device, so that it is preferred that minimal data be permanently stored on the user device. Accordingly physical storage resources of limited user devices are preferably allocated to AM rather than permanent storage.
Advantageously, a user---rofile can also be stored on the host computer facility so that
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if the user device is lost, broken or stolen, a new device can be automaticallv reconfigured across the network linking the user to the host facility, so that the application behaves the same.

Preferablv such a host computer facility also provides customized services to each user device, performing "user-adaptive" functions for that device, as described herein, to adapt it to its authorized user or user's prescribing behavior and improve the level of assistance provided to the user. Employing such off-loading techniques, permanent storage capabilities of the device can be minimized in favor of faster AM storage capabilities.

The screens are designed to be non-intimidating to computer-inexperienced professionals and to present familiar infon-nation and terminology to them while avoiding specialist computer jargon. Individually, they are easy-to-use for novices yet rapid enough for experienced users. Collectively, they provide an appealing system interface which can flexibly integrate into a physician's personal work flow.
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In addition, the screens are laid out in the manner of appealing logical forrns that echo familiar data formats encountered by a physician in their day-to-day work. An important objective is to make the screens self explanatory within the professional's normal terms of reference so as to avoid any need for access to help, although of course, HELP buttons can be provided if desired and extensive help documentation can also be provided. ystern utilities such as indexing, setup and purging are either concealed from the user or removed for execution on a remote host computer facility.

Data integrity and availability responsibilities are also delegated to the host computer facility, or its remote data suppliers. Thus data

saving, archival, backup and datareplication functions are host facility responsibilities, not concerns of the user.

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The system is designed to require a minimum of actual text or data entry. o far as possible, item entry is effected by selection from lists of items, for example by highlighting an item, then clicking a mouse, or more preferably penning, to activate an item.
The prescription management system is made as user-friendly to physicians as possible, for example, by using familiar professional terminology and abbreviations.

Thus terms such as "Patient" or "Pt", "Drug" or "Rx", "Condition" or "Dx" and "Treatment" or "Tx" are used rather than confusing generalities such as "subject" and "item" that often appear in generic software. The Prescription Management ystem shown in this embodiment of the invention has been designed for use,%vith small portable personal computers, especially hand held devices known as personal digital assistants. Those skilled in the art will understand that the svstem can readily be used on or adapted to other hardware platforins, for example, a physician's desk top computer and can be expressed in different software interfaces from that shown.

eferring now to Figure I the system entry screen illustrated has a user-custornizable button bar IO which has been set with a conventional Quit button 12 and a Help button 14, along with a Mail button 16 for accessing an electronic mail ("E-Mail") system, a Prescribing button I 8 for accessing the prescription management system embodiment of the invention, an Encounter button 20 for accessing a patient encounter management system (not further described herein). Ans Svc button 22 accesses an answering service screen (not shown), which as a convenience function can be dynamically linked via the host computer facility to log incoming calls for the user. The answering service is preferably intelligent and prioritizes, by flagging or displaying, patient- or treatment-related calls, for example those from a pharmacy, while screening out or de-prioritizes less relevant calls.

HistoEy
-.:cognitive drug and condition fistin
A Doctor's Lists button 24 accesses a more or less complex display of patient condition and therapeutic drug lists. Preferably, the drug and condition lists are linked together to associate a drug with one or more conditions for which it might be prescribed and, in most cases to provide the physician user with a conveniently displayed, concise selection of drugs for treating any particular condition. In a preferred feature of this invention, the system has a user-adaptive character and adapts

itself to the user's habits and prescribing patterns so as to service the user more efficiently. To this end, the drug lists or the condition lists, or both, are system-modified with use to reflect the prescribing frequency of particular drugs or the frequency of occurrence of particular conditions. Thus, more frequently prescribed drugs or more frequently encountered conditions can be presented to the user physician in a more prominent manner or more immediate manner than ones foundbythesystemtobehistoricallviesscommonintheparticularuserprescribing environment. In this wav the svstem becomes more valuable with use as the drug and condition lists develop into personalized lists featuring tile user's preferences.

With such cognitive features the inventive system is effectively cognizant of ongoing 1 5 prescribing activity. It comes to know its user's environment and preferences, can adapt itself to any number of specialist situations, and can, if suitably equipped, subtly prompt the user, online with original, relevant, but elusive inforrnation derived from the user's computer-memorialized practice experience. For example tile system may prompt the user that the last time Drug X was prescribed for Condition Y, Patient Q reported adverse reaction Z. Where the host computer facility documents a catalog of known adverse reactions to system-listed drugs, a system enhancement can report new adverse reactions to the user or centrally, to the host computer facility, by tracking logged patient conditions and relating them, where appropriate, to a previous prescription . In similar manner the system may log drug-drug interactions, which interactions can also be associated with a target condition or conditions. Many other valuable retrospective statistical studies and analyses are made possible by deployment of the invention, as will be apparent to those skilled in the art. While such studies are potentially of immense public value if widely implemented, careful controls will be required to avoid reporting unrelated conditions as adverse drug reactions.

With time, as it adopts appropriate specialist prescribing patterns, the user-adaptive prescription management system of the invention can be just as relevant and useful to, for example, a specialist in tropical medicine as it is to a pediatrician. This desirable result can be achieved without encumbering either specialist with the needs of the other.

Those skilled in the art will appreciate that the invention's cognitive, user-adaptive features employ significant programming routines and procedures and are quite different from common, user-responsive software defaults which merely offer defaults pre-set by the user or simply show the last used item, file or the like as a default.

If desired, the user's prescription management system can have built-in, online, statistical reporting functions enabling a physician user to review their, or others, historical experience with a particular drug or condition and providing online historical review of anv other activities or data entrusted to the svstem.

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Of scientific note is that the system is privy to and operates at the confluence of three powerful emergent data streams: encyclopedic data on therapeutic agents intended to moderate particular conditions or patient problems; data on individual prescriber activity using sldll and judgment to diagnose conditions or problems and make prescribing decisions selecting and applying therapeutic agents to diminish diagnosed conditions; and patient history data recording not only prescribing decisions but also the results of those decisions (see the description of Figure 12, below). Thus, the system captures not only prescribing activity but also the presmfhe?s intent, the problem or condition targeted by the prescriber in specifying a particular drug, and can track the success of that intent. The linkage of treatment with condition treated captures the reason why the doctor took the prescribing action that was taken. This intent may, and can legally, be different from approved FDA therapeutic indications for a drug.

Of commercial note is that the foregoing data may be aggregated for multiple users, for example by the host computing facility, for market research purposes. Also, an individual user's prescribing patterns may be reviewed by the user or by others. For example, drug benefits companies, can review the user's prescribing patterns for formulary compliance and respond by encouraging better compliance, where appropriate. elease of such data to third parties can be controlled to safeguard the privacy of the prescriber, or other health care provider, by prescriber-determined data access protocols specifying who, or what organization, department or group, may access what data, when they may access it and what they can do with it. For I 0 example, one physician may permit academic use for research studies and prohibit commercial use while another may permit either.

As will be described in more detail subsequently, a range of optional features, for example the answering service and e-mail features mentioned above, or other 1 5 communications features, can be made available from button bar IO providing the user,with user-configurable means to customize the system to their personal needs and tastes.

Intelligent drug-selection procedure
Iceptical prescribers are encouraged to adopt the prescription management system of the invention, by its ability to bring to the

point-of-care, in readily utilizable form, a battery of relevant drug-specification information and important patient-related information, much of which is not readily accessible at the point-of-care by conventional means.

Preferred embodiments of the invention achieve this desirable result by providing an intelligent drug-selection procedure which is supported by transparent connectivity to multiple remote proprietary information systems at the point of care, enabling a physician to draw upon the following categories of data.

i) physician-user prescribing-frequency data;
ii) patient drug formulary information as to a drug's status with a patient's
drug benefits provider;
iii) drug dosage characteristics, for example, form, size, route of administration, amount, frequency and the like;
iv) drug-specific treatment information as to condition-related efficacy, and
preferably as to contraindications and adverse reactions;
v) relevant patient history information as to current and previous prescriptions, and preferably also, pursuant to the teaching of the present invention, problem-history information; and
vi) laboratory and other diagnostic test information related to the patient's
indications, to dosing, to therapeutic choices or to specific drug selections.

Preferably, this data is brought to the point-of-care by relying upon retrieval from 1 5 remote source databases at remote facilities responsible for capturing original update
data, and not by relying upon redundant non-source data
requiring constant synchronization with source data to remain current.

Diagnostic tests
Items i)-v) above, will be described in considerable detail hereinafter. With regard to diagnostic tests and procedures, for example radiology, the invention contemplates electronically bringing relevant information to the point of care to assist health care providers make informed decisions. uch diagnostic information may comprise recommendations for clarifying a tentative diagnosis, or choice of diagnoses, or may comprise diagnostic results that can be used to make more informed therapy decisions and, in particular, to make better therapeutic drug selections. Body system function tests, for example renal or liver function tests are clearly valuable to a drug selection process, since renal and liver condition are important in detennining dosages of some medications. Other

therapy-relevant diagnostic deten-ninations can usefully be presented at the point of care, by means of the present invention, for example, drug-level determinations can enhance dosing decisions.

Patient encounter program
A useful, prescription management system-compatible patient encounter program can begin with a patient selection screen such as that of Figure 2. The patient selection screen of Figure 2 can be activated by any one of multiple programs which may, for example, be initiated via the svsteni entry screen of Figure 1, but could be independent, free-standing programs or any other program for which the ability to create, update and modify a patient-specific record or a patient history is valuable.

Preferred embodiments of software procedures (or programs) associated with the novel patient record selection procedure illustrated in Figure 2 can access multiple remote databases to retrieve patient records, for example, by using the host computer facilitv, and can also post new patient records, and updates, created locally by the physician-user, to the multiple remote databases in real time, or in batch mode.

Patient record source data
ource data for a typical patient record may be distributed across multiple, geographically dispersed, electronically incompatible, remote databases maintained for example by drug benefit companies, insurers, laboratories, medical facilities, diagnostic testin facilities and health maintenance organizations, including
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government agencies (MEDICAID, MEDICA E, etc.) and health care providers themselves, that have serviced the patient in the past. E nown automated patient record systems either ignore such remote data andwork only with data created at the maintaining facility or vertically integrated health care organization, or create and maintain duplicates of the remote data.

till more preferred embodiments of the invention provide substantial savings of resources, time and effort by using only source data for patient records, minimizing creation of multiple redundant local databases that require constant synchronization with remote sources if they are to remain accurate and up to date.

The invention also provides novel data-retrieval network systems to retrieve relevant patient data elements from multiple remote heterogenous primary source databases.

Preferably, every time a host computer facility receives a call from a user device for a patient history or patient record, relevant data elements, for that record, or a record component (e.g. the most recent

six-month or twelve-month portion), are retrieved from remote source databases, dynamically assembled, or integrated, into a virtual patient record, as described above, and delivered to the user device as an integral system data set. Alternatively, record assembly, which does not require undue hardware resources, can be performed on board the user device.

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The record is viewed and may be printed out by the user, with patient authorization, but does not need to be permanently stored.

The host computer facility responsible for dynamic assembly of the virtual record
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5 logs the time, date and calling user to provide an audit trail of access to the patient's record, but does not commit the record to permanent storage. After use, the virtual patient record disappears, although it can be reconstructed archivally.

If the record is required again, it is assembled anew, thereby incorporating any updates that may have occurred in the interim, for example changes in drug benefit status, insurance coverage or the like, newly ge nerated laboratory, radiology or other diagnostic results, or other, e.g. emergency, prescriptions dispensed. The act of assembling a record externally of its sources immediately dates the record: it is cut off from any updates, and therefore liable to become incomplete, obsolete or dated.

Virtual patient record assembly, as described herein, avoids this problem making local storage of patient records unnecessary.

Transactions arc archived by the host system to provide a complete transaction history, so that past activity can be reconstructed. uch a data-reconstruction capability to provide clear hind vision of the patient's record at any given time is an important medicolegal capability. That historical version is preferably reconstructed
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from a transaction log and assembly of timed and dated record elements, or segments, in a manner not unlike that used by version control software.

5 Creating a virtual patient record permits optimal data currency and accuracy and, by avoiding unnecessary redundant copies of patient data minimizes liability for misuse or unauthorized access. Patient confidentiality can be maximized and is verifiable by the system-generated audit trail.

I 0 Preferablv for individual record elements to be admitted to the system, they are required to be at least dated and preferably also to be timed at source, such timing and dating relating to whatever event created the record. In addition to its value as an integral record characteristic, chronological data is useful for retrospective archival reconstruction of a record as it existed (in its elements) at any given point in time.

5 This can be achieved by retrieving record elements, as described above, using a suitable date filter and if appropriate, a time filter, to include only those (or selected ones of those) record elements that existed at the desired given point in time.

uch an archival retrospective record reconstruction capability is a highly desirable adjunct to the virtual patient record described herein permitting full creation and examination of anv desired historical records, such as may be required for review or legal purposes.
Using the above-described method of dynamic retrieval from remote databases across a data-retrieval, record-integrating network, source database proprietors can remain wardens of the only copy of that data and obtain patient authorization to be the sole repository of that data.
Laboratories can keep laboratory records; insurance companies can keep insurance records; hospitals can keep hospital records; and health maintenance organizations can keep their own records; without ever having to release copies of these records into external electronic storage by third parties, with the securitv hazards attendant upon such releases.
Any electronic release made externally using the data access control features described herein can be assured of always being authorized by whatever entity, be they patient, physician or organization, that has proprietary rights in the data.

Figure 2: Patient selection screen
Upon selecting Prescribing button 18 by clid<ing or pen contact, a patient selection screen, for example as shown in Figure 2, is displayed as a preliminary to prescription management functions. eferring to the patient selection screen of Figure 2, the I 0 name, age, gender, and social security numbers of patients who have authorized the user physician to treat them, or to access the svstem on their behalf, are listed under
respective column header buttons, namelv, Name button 26, Age button 28, Gender button 30 and Social Security button 32.

1 5 Lists can be scanned, or text entries made in a blanic search box 34 at the top of the screen, using string or full name searches to locate the desired patient or to review the patient list. Column headers 26-32

can be clicked or touched to sort the patient list on any of those
Fields and activate search box 34. earch box 34 is linked to the sort
fields so that, for example, if the listing is sorted by social security
number then 20 alphabetical entry attempts are rejected from search box
34 and numeric entries are used as social security number locators. The
characters can be keyed or system provided from pop-up screens, or voice
or handwriting recognition may be employed.

New Pt button 36 activates a new patient entry bar, while the Ok button
39 accepts
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a highlighted patient selection and advances to the prescription
management screen of Figure 3. Cancel button 38 returns to the system
entry screen of Figure 1.

If desired, preliminary selection of groups of patients can be made by
providing various patient lists, for example "TodavIs Patients",
"In-Patients", "Out-Patients", 30 "Private Patients" and the like. tich
patient lists are preferably svstem-maintained, on an ongoing basis,
using the latest data available to the system and preferably
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enable the user to select a convenient group of patients that has a high
probability of including the next patient or patients to be encountered,
thereby speeding access and
retrieval of a desired patient record. Where the user ty
. pically encounters patients in
groups, for example one group in an out-patient clinic and another group
in an inpatient clinic, such grouping of patient records into lists also
facilitates organization by a host computer facility of display data into
small batches that can more rapidly be communicated via limited capacity
copper wires and modems and are of a size that can convenientiv be held
in AM on a small, portable user device.

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Patient Data Securi
Critical to public confidence in the prescription management system of
the invention are issues of securitv, since the svstet-n requires access
to personal records. Many people will fear unauthorized access to or use
of their personal information.

1 5 Preferably, the invention provides careful controls to alleviate such
fears and to prevent unauthorized access to a patient's data or to their
physician's prescribing profiles.

Preferablv also, the svstem, or an associated support network, provides
data access controls such that the only accesses that can occur are those

that have been authorized or preauthorized, at a point of care or elsewhere, in accordance with security profiles on the network established on behalf of data-proprietor entities such as patients, physicians or organizations. It is further preferred that the entitys security profile, or filter, details what data can be accessed, when it may be accessed, where it may be accessed and bV whom it mav be accessed.

Various suitable data access control measures will be known to those skilled in the art and considerable security can be obtained by using more or less complex identifiers for patients or for physician-users of the system or for both.

Patient records should use a standard identifier to be clearly and distinctly identified with a confidence level appropriate to the expected patient population in the lifetime of the system so that the records of patients with similar or identical names are not confused. If desired, a coded alphanumeric patient identifier (not shown) may be used. Alternatively, or in addition, other unique patient identifiers such as social security numbers may be used alone or as secondary references in conjunction with patient names and the like.

More relevant to security is proper identification of a user to whom patient data is I 0 released or from whom new data is received bv the host computer facility. While numeric or alphanumeric user identification codes provide some level of security, higher levels are provided by using graphic, photographic or fingerprint recognition to identifv a svstem user.

1 5 More preferred embodiments of the invention can ensure a still higher level of confidentiality by automatically maintaining a complete audit trail of access to patient data. Preferably the audit trail details, for every access, who or what organization accessed the record, what part of tile record was accessed, when it was accessed (both date and time) and what was tile purpose-of viewing the record.

Thus, associated with every patient record is a timed and dated log of every physician user, organization or health care professional accessing that record. If desired, the log can be reported, or made available to a patient, on request, for example through online access (with careful security controls), via print or fax, and so on.

Patient-directed control of the flow of their own data, a novel concept in medical or health care information systems, can be achieved by centrally inputting at the, or a, host computer facility patient-generated record-access specifications to determine which users, or user organizations or departments (for example clinics), can access

what data during what period and what uses can be made of the data.
Clearly, such specifications must not deleteriously restrict physicians
in the execution of their professional missions. uch record-access
specifications or profiles could be maintained at a remote database
rather than the host computer facility. Thus, access to their records is
controlled by patients and individuals and organizations can be given
patient-defined, selective access or access based on a need to know, or a
patient may block access to all data flow, if they wish. In emergencies,
physicians may be able to override a patient security block, but such
events are recorded so that any abuse can be monitored and action can be
taken to discourage abusers.

MD-Related Data Securijy

Many similar.data security considerations apply to prescriber-related
data. Used comprehensively, as it is intended to be, the svstem is privy
to full particulars of a physician user's professional prescribing
behavior, day in, day out, potentially throughout their career. vstem
resources may be used to compile any desired historical record of a .
user's prescribing activities. Patient-confidentiality aspects of this
data have been addressed above and can be satisfactorily managed by
controlling access to patient-related data in accordance with a patient's
previously, or currently expressed wishes, as described herein. In
addressing physician-oriented prescribing issues, the historical record
may be rendered patient-anonymous by stripping the data of recognizable
patient identifiers, or aggregating the data. The resultant historical
prescribing data can communicate significant information about the
prescriber, is personal and proprietary to the prescriber.

Pursuant to this invention, the prescriber's rights in their historical
prescribing data are protectable in a manner similar to the protection
affordable to patients, by providing prescriber-determined access control
specifications detailing permissible levels of third-party access to
prescriber data. uch prescriber data access control specifications can be
stored in individual files on the network and can comprise as to who or
what organization, or type of organization may access what data, for what
purpose and for what period of time such access right may be effective.
Clearly, multiple levels of access control may be described to anv
desired degree of complexity. User preferences may include user
authorization for data access by various third parties for example health
maintenance organizations (HMO's), hospitals, government agencies,
managed care organizations and so on.

A particular group to whom a prescriber may wish to vield access Tights
comprises collective bargaining associations, for example independent
practitioner associations, preferred provider organizations and physician
hospital organizations. Preferably, all accesses to a prescriber's data
are system stamped with a date, time and accessor ID, to create an audit

trail of such accesses, sin-tilar to the audit trail left by accesses to
IO patient data.

ystem-determined access control can be invoked, whenever a prescriber
data access request is received, by referencing the prescriber's access
control file and permitting or denying access in accordance with the
file's specifications.

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Prescription creation screen 39
eferring to Figure 3, prescription creation screen 39 has a full array
of useractivatable buttons enabling a physician to draw on powerful
resources within the prescription management system and supporting it
in the host computer facility and associated data-retrieval network, as
will short1v be described. Near the top of screen 39 is a patient
features bar 40 below which a prescription features bar 42 coordinates
all features necessarv to review current therapy and order changes in
treatment, or order new treatment, for the selected patient. A
prescription history zone 43 extends across the middle of the screen,
the lower screen portion contains a prescribing zone 44, and a screen
title 45 appears at the top of the screen.

Patient features bar 40 comprises a Select Patient button 46, a selected
patient indicator 48, in this case Mary Harrington, a patient Problems
button -50 and a patient Allergies button 52. Beneath Problems button 50
are displaved Marv Harrington's currently active problems 51 or
conditions, shown here as pharyngitis and bronchitis. Beneath Allergies
button 52 are displayed Marv Harrington's known allergies. Pressing or
otherwise activating Problems button 50 or Allergies button 52, opens a
window or screen listing problems or allergies from which a physician, or
other professional user, can select new problems or allergies to add to
Mary Harrington's record, or delete ones that are no longer active.
Optionallv, systemprovided problem or allergy libraries may be organized
into multiple lists with button 50 or 52, respectively, opening a list
selection box as a preliminary to displaying a selected problem or
allergy list.

Problems or conditions 51 and allergies 53 are here displayed as a
helpful notation for the prescriber and do not become prescription
elements as a result of being selected for display in this part of the
screen. However, selections made here are functional in that selected
problems 51 (conditions) will become defaults or preferred choices in a
subsequent condition specification procedure and tile system will review
any drugs prescribed for relevance to allergies 53.

Prescription features bar 42 comprises an Rx History button 54, an Rx

Options button 56, an Updating indicator 58, an Rx Info button 60 and a Renew Rx button 62.

Prescription history zone 43 displays those historical prescription details that may be relevant to a current prescription and has a Condition field 64, a Drug field 66, a Size field 68 a Dosing field 70, a generic flag 72, an Expires field 74 and a Mine field 76, in which the various characteristics of patient Mary Harrington's previous prescriptions are listed.

Prescribing zone 44 comprises three active buttons, New Rx button 78, Send Rx button 80 and Close button 82, below which extends a prescribing header bar 84 which contains Field identifiers for data entry of a full complement of prescription details. Available prescription detail Fields comprise a Condition field 86, a Drug field 88, a Generic field 90, a Form field 92, a Size field 94, a Route field 96, an Amt (Amount) field 98, a Refill field 100, a Dosing field 102 and an Expires field 104.

Multiple lines of the selected patient's prescription history are listed in patient history zone 43 in the middle of the screen for convenient review by the physicianuser, and possible renewal, with scrolling or paging of extensive histories. Depending upon the patient's previous whereabouts and service providers, individual lines may come from multiple remote sources. tich histories are preferably compiled by the
hostcomputerfacilitvinresponsetoacallfromtiietiserdevice(seethedescriptio n of Figure 16).
Prescribing zone 44, lower down prescription creation screen 39, allows a physician user to select and prescribe drugs and dosages, for tile selected patient, in this case Mary Harrington, and to transmit the created prescription externally across a data network to other interested and authorized parties for prescription fulfillment, patient record updating and tile like.

Select.Patient button 46 returns to the patient selection screen of Figure 2 for selecting a different patient from one or more lists. Preferably, Select Patient button 46 draws up a "Today's Patients" list or whichever patient list tile user last selected from, or a default, user-selected patient list, and provides the options of selecting a new patient from alternative patient lists.

Problems button 50 brings up a patient problem history information screen such as that shown in Figure 12 (to be described) in which a historical record of the patient's individual symptoms and diagnoses is listed and to which new problem reports can be posted. To maintain data integrity,

and as a legal safeguard, historical information is not editable but may be supplemented, for example by reporting the subsequent status of a problem as (still) active or inactive. Preferablv, anv such additions to the record are stamped with the identity of the reporting physician, providing valuable elements of a treatment decision-making audit trail.

The patient's drug-related allergies, or drug reactions, are brought up in possibly editable form (screen not shown) by activating an Allergies button 48 and may be automatically system updated, if d6sired by adding newly reported drug reactions and allergies. Desired personal or drug records relevant to possible allergies of this patient may be summoned from the host computer facility, which may in turn call on the remote database data-retrieval network for records or record elements.

Rx History button 54, scrolls, drops down, or otherwise accesses any additional patient historv lines bevond what will fit in prescription history zone 43 and may introduce vertical or horizontal scroll bars, or both, into zone 43, enabling the user to display any desired section of a patient's prescription history in zone 43 with the top line of the history highlighted. Any desired prior prescription line displayed in zone 43, can be highlighted by clicking or pressing on it.

A highlighted prior prescription can be automatically renewed by clicking or pushing an Renew Rx button 62. Typically, prescription creation screen 39 opens with the most recent prescription highlighted for possible renewal. Activating Renew Rx button 62 posts a highlighted prior prescription into prescribing zone 44 for automatic renewal, after editing, if desired. enewal of any prior prescription can thus be effected in as few, as two user steps by pressing Renew Rx 62 to post a 25 highlighted previous prescription to prescribing zone 44 and a single further action to complete a prescription from there. If desired option buttons such as Renew and Send Last Prescription or Renew All Active Prescriptions can be added.

Pressing header buttons Condition 64, Drug 66, or Expires 74 causes the drug history display to be sorted bv the selected header enabling the prescription history to be evaluated according to a particular parameter. This feature is of particular value for patients with long and complex treatment histories.

An important novel feature of the inventive prescription management system is the abilitv to associate a specific patient condition with each drug prescribed. By capturing detailed information on every prescription the system automatically builds a novel patient medical record having new uses in evaluating individual patient treatment and in enabling powerful new, multi-center outcome studies for evaluating therapies in

various populations of patients.

By deploving the inventive system regionally, nationally or in some other population area, and emploving the preferred methods for retrieving patient data from remote sources, as described herein, a complete patient record of all activity within a region can be built. Preferably this is a virtual patient record dynamically assembled only 1 5 from original source data, which, as described above, is maintained in component form at multiple distributed source databases, is retrieved therefrom across a dataretrieval network from which the source databases can be accessed, and is compiled or assembled into a single virtual or transient record that appears to the user as an integral system data resource.

Outcome studies, prescril2tion cost savings and drug alerts

Patient histories generated by the inventive sVstem can show not only the drugs prescribed, but also the conditions for which they were prescribed, allergies, demographics, insurance coverage, treating health care providers, and so on. 14' nown medical management systems do not provide listings associating each prescribed drug with a patient condition or problem, as reported to, or diagnosed by their physician.

Careful review of a patienes record for relationships between amelioration of problems and prescription of particular drugs can provide important information about the efficacy of a drug for a particular problem in a given patient. eview of a physician's prescribing record, detailing the various drugs selected to treat the different conditions exhibited by the patients encountered in the physician's daily practice, can reveal valuable information about tile physician's prescribing practices and the degree to which they follow fon-nularv guidelines.

This information is clearly of value to the individual physician and can, if desired, be enhanced by including in the problem record a condition severity rating, enabling declines (or increases) in severity to be reported. The resultant patient prescription history, replete with dated information as to patient problems, what drugs were I 0 prescribed to treat those problems, what forms, routes of administration and dosages were used and, by implication from the timing and nature of subsequent problems, what the outcome of that prescription was, provides a very attractive treatment evaluation tool to a physician, and a powerful inducement to any professionally conscientious physician to use the prescription management system of tile invention.

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Implementing the invention on a wider scale, valuable new outcome studies and clinical trials are easily, or even automatically, performed. One of many problems in successfully implementing the herein described

prescription management Svstern on a large scale is one of funding the system. Medical cost structures, with their reimbursement svstems leave little scope for expenditure on aids to overall practice improvements which may have to be squeezed out of tight overhead budgets.

Accordingly, significant cost to the physician user, or user's medical facilitv will be a major deterrent to system adoption. Preferably tile system is provided to prescribing users on a low-cost or no-cost basis with funding from outside sources.

Implementation of the invention is expected dramatically to reduce tile overall cost of prescriptions and this saving has been estimated to be from 20 to 40 percent of total prescription costs. avings will accrue initially to tile drug benefit management companies who reimburse the direct costs of most prescriptions, but can be expected eventuallv to be passed to corporations and consurners by way of lower drug benefit rates. uch savings realized on a national scale would amount to many billions of dollars and provide an avenue of reimbursement for system proprietors. In the early 1990's, the cost of prescription drug benefits is one of the fastest rising components of all health care costs.

Outcome studies produced by the system may have substantial value to various parties, and their sale can support system costs, as may formulary compliance savings. For example, drug efficacv data is of value to pharmaceutical companies, as is early warning data from reliable specialists regarding adverse reactions. ubject to I 0 confidentiality and other relevant controls, such data can be automatically compiled and readily supplied by system management, requiring only approval, not active participation by involved physician prescribers. Equally, the svstem mav facilitate clinical trials by identifying health care providers or prescribers who would be likely participants in trials, based upon their having frequently diagnosed relevant conditions, or specified relevant drugs, as shown by their historical prescribing profiles, or relevant patient histories. uitable patient pools can be identified similarly.

Organizations participating in outcome studies, for example health maintenance organizations, insurance companies, hospitals, physician alliances and the like, and may pool their data but may not wish to reveal certain proprietary data. By employing data access control methods for accessing such organizational data, such as the methods described in detail herein for controlling access to patient's rights, the system of this invention can enable organizations to control what data they release.

To implement such clinical trials, additional information required for collection can be obtained by flagging selected prescribers' profiles to

trigger additional on-screen routines so that whenever a trial-related drug or condition is selected by the prescriber, they will be asked to supply necessary additional information. For example, whenever a prescriber participates in a trial relating to treatments for gastritis, the system can request information as to whether certain tests were performed, and what were the results of those tests. Thus, the test drug might be appropriate for, or be in trials relating to, gastritis testing positive to H. p
.ylori,
whereas a different drug would be indicated for Hp
.ylori-negative gastritis.

The system can also provide, preferably from source databases, complete prescription drug disclosure requirements as set forth by the FDA, including full cautionary information, for example as is now set forth in the Physicians' Desk eference (Medical Economics) and Physician's Gen x (Denniston Publishing) knowledge of I 0 which by the prescriber may be necessary to avoid malpractice liability, and dissemination of which may limit a drug manufacturer's liability. Efficient promulgation of drug disclosure information to system users is tantamount to publication, yet can be more current than any printed document, and may be accepted as an alternative to hard copy publication or supersede it.

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In addition, the system provides a valuable means for government agencies and others to communicate important messages, such as drug warnings and alerts, quickly and directly to physician users. Electronic mail accessed via Mail button 16 can be used for this purpose, and mav include priority flags triggering screen alerts, but a much more powerful route for communicating warnings relating to particular drugs is to associate the alert with system infon-nation on the drug so that when a user calls up the drug in question, they receive the warning or alert, or other special message.

In the extreme case of withdrawal of a drug from the market, that fact can immediately be communicated to system users. Thus a drug can be withdrawn from the market the same day by making a system entry preventing completion of a prescription for the withdrawn drug. Alternatively, a warning can be posted directly to the prescription . Current users of the medication can be identified from prescription history records, referencing not only drugs prescribed, but also prescription expiration dates. Both the patient and their doctor can be notified immediatelv. In this case, electronic mail is a preferred route for notifying the physician.

elative cost-to-benefit data can also readily be prepared in outcome

studies when individual drug costs are factored into the data, and such
cost:benefit data can, in some circumstances have very substantial dollar
value to drug benefits management companies whose objectives are to
maximize the quality of care while minimizing the cost of that care.

IO Pharmaceutical and managed care companies can gain marketing benefits
from use of the system to introduce new drugs or new uses of old drugs to
physicians, in a relevant manner, at a moment of peak interest.

Other benefits can be derived from outcome studies using the novel
drug-prescribed 1 5 and condition-treated data records provided by the
prescription management system of the invention. For example, the
appearance of a new patient problem may be insignificant when associated
with prior prescription of a particular drug for one patient, but may
gain significancewlien repeated for a number of patients.
Optional system enhancements may enable post-introduction market
surveillance of new drugs to be -conducted for adverse outcomes to the
treatment of a specified condition or conditions. For example the system
may monitor patients reporting new problems after having been prescribed
the new drug in question, refer such new problems to the physician user
to qualify them for medical relevance and then statistically compare a
collection of similar reports with data on a pool of similarly treated
patients for significance.

Continuous post-market-introduction monitoring of a drug in relation to
the treatment of conditions is possible, and an end-to-end solution to
the problem of managing unanticipated problems arising with new drugs can
be provided: the system provides a vehicle data collecting relevant
data; parameters and a means for analysis of that data; and a means for
disseminating alerts and advisories regarding newly discovered problems.
The same vehicle is used for all three steps.

With such a system enhancement, one specialist pioneering a new drug for
a particular condition may provide an early warning of adverse reactions
not identified in clinical trials in a manner not heretofore obtainable,
because of the difficulty of coordinating prescription and diagnostic
data.
Quickly and conveniently presented at the point of care, as an integral
part of the I 0 prescribing process, in the manner achieved by the system
of the invention, this information can be of immense value to a physician
when treating a patient, widening the physicians' choices beyond their
own field of knowledge (by suggesting new drug information) and helping
the physicians optimize the prescribing process.

5 Another advantage of the invention is that each physician user
inherently and easily supplies critical enabling data for outcome studies

as part of the prescribing process.

No extra effort is required by the physician to make the data available for studies.

One potential difficulty in making such studies is the existence of legal barriers to aggregating patient data into studies without specific patient permission. While this might be obtained on a piecemeal basis or by the prescribing physician, a much better solution is provided by centrally maintaining patient directed patient-recordaccess specifications, as described above. The system can then include only those records of patients agreeable to becoming study participants in such outcome studies.

The historical drug-prescribed and condition-treated records obtainable by using the invention can provide a basis for condition-based treatment guidelines developed by drug formularies. This novel data provides anew vehicle for outcome research for managed care, leading to new approaches to cost-effective prescription treatments.

30 Compilation of an extensive or national database of (patient-anonvi-nous) records providing a statistical historical listing of drugs prescribed versus associated conditions for which they were prescribed would be in the public interest and of considerable value, so long as patient-confidentiality were maintained. Widespread adoption of the present invention can help achieve this desirable goal. It is relevant to note that FDA regulations only pen-nit a drug to be promoted for approved, specific therapeutic purposes but physicians are professionally free to prescribe an approved drug for any condition for which they believe the drug to be effective or useful so that, failing specific point-of-care diagnostic information, no assumptions can be made as to the treatment objectives of any particular prescription . I 0 Accordingly, prior to the present invention, statistical prescribing data have generally lacked knowledge of why a physician prescribed a particular drug, and such data is, in most cases, not useful for outcome studies and cannot be related back to other patient-specific variables present in the patient's medical record.

I 5 Prescril2tion histoW record
eferring to the prescription history zone 43 of the Figure 3 screen, under the Condition field 64 is listed a condition reported as active when the drug was prescribed. Drug field 66 may be a generic name or a brand name. The Size field 68 is the dosage size. Dosing field 70 shows the dosing frequency. TI-ie "G" flag 72 is for generic and is a simple yes/no indicator. An Expires field 74 displays an expiration date system calculated from the prescription quantity (not shown), the size and the dosing rate and indicates the day on which the prescription will run

out.

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The last column, Mine field 76, is a yes/no toggle flag indicating whether the prescribing physician was the current system-designated physician user ("Y" = my prescription) or some other physician ("N"). Another prescribing physician's details and other data relevant to a previous prescription can be obtained by pressing Rx Info button 60, or double-pressing or -clicking on the appropriate prescription history line, to draw down a prescription information screen, for example, as shown 30 in Figure 12. Additional available options, if any, can be accessed through the Rx Options button 56.

Update button 58 can be a simple blinking indicator alerting the user that their device is communicating with the host computer facility and actively processing a local update. To indicate additional time taken accessing remote databases, the message can change to " emote etrieval", if desired. Additionally, Update button 58 can activate various update options, selectable from a menu, if desired. For example, Update button 58 may offer a selection of different sources from which to update the patient's prescription history. While a preferred objective of the invention is that the prescription management system obtain a comprehensive, nationwide update of any previous prescribing activity regarding this selected patient, considerations of system speed, system development or marketing considerations may make it desirable to offer patient prescription histories drawn from all prescribing activity in a more limited geographical region, for example, local or regional updates local network updates or capability to update from the physician's institutional or office practice infori-nation systems.

New prescri12tions
Activating the New Rx button 78 highlights the first available blank line in the lower portion of the prescription management screen for creation of a new prescription by a physician-user. During the prescription creation process, the user receives intelligent decision support from the system of the invention. Preferably, the system proffers the prescribing physician comprehensive relevant prescribing data to enable creation of a new prescription intelligently, in an informed, manner with routine look-up functions being fully automated so that professional time spent on routine chores is minimized or eliminated. To this end, data entries available via both Condition button 86 and Drug button 88 are selectable from extensive lists, as %ill be described hereinafter.

As described above, the svstem provides the user through their interface device and a linked host computer facility, transparently connectivity to multiple remote

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proprietary databases for retrieving necessary data such as drug and condition lists.

Pressing (or clicking on) highlighted fields beneath the headers in prescribing header bar 84, in most cases, activates pull-down menus, or data entry scrolls. Generic field 90 is merely a toggled flag while Expires field 104 is a system-calculated field.
Although provision can be made for a physician to make original entries, the preferred embodiment provides a comprehensive selection of sy'stem-generated drug prescribing data from which the user may make selections.

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If the user knows the drug they wish to prescribe, the drug name may be keyed in or, preferably selected by highlighting and clicking from one or more intelligently maintained lists presented in drop-down menus to post it to the respective highlighted field under Drug header 88.
Alternatively, the user can select a 5 condition from a condition list and make a drug selection appropriate to that condition from a drug selection screen such as those shown in Figures 4 through 1 1 as will shortly be described in more detail.

Generic flag 90 is a simple yes/no indicator which is linked to eac drug
se ection to
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approve generic drug substitution for brand name drugs by the pharmacist, if such substitution is permitted by state regulation.

PrescriRtion quantification
The Form, Size, Route and Amounts headers 92-98 are linked to the drug selected and bring system resources to bear to enable a prescriber rapidly to quantify the prescription with appropriate dosages that can be filled at a pharmacy, without undue difficulty. Activating any one of the fields under headers 92-98 drops down a menu, which menus together offer a selection of all known formulations of the drug selected, as provided by the manufacturer, using comprehensive drug inventory data accessed via the host computer facility or its supporting data-retrieval networks.

The entry for Form field 92 may be selected from choices such as capsule, caplet, tablet, and liquid. That for Size field 94 might be a selection of 50 mg, 1 00 mg, and 200 mg and the Route field 96 selections might be "PO" for per oral, by mouth, "P " per rectum, "IV" for intravenous, and so on. The displays are related and intelligently selected to display relevant options. Thus, for example, if "PO" is selected as the route of

administration, only PO do@age forms are displayed. On the other hand, if PO oral forms are selected, "PO" appears as the route of administration.

The Amt field 98 is the amount or quantity of drug to be dispensed in the I 0 prescription , for "ample 30, 50 or I 00 capsules or 50, 55, or I 00 ml of liquid.
Refill field I 00 shows the number of times refilling is permitted and Dosing field 102 has two columns, one being a numeric designation of a number of tablets, caplets or liquid dosages to be taken at any one time and the other bein an alpha
I 9
indication of the dosing frequency such as QD for daily.

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In an optional, modified embodiment of the invention (not shown), the system can calculate or suggest effective dosages for a selected drug, or a narrow range of effective dosages, according to dosage-relevant patient characteristics, for example, height, weight, age, sex, pregnancy and the like, taking into account the physical formulations in which the drug is known to be available. While these characteristics might be entered or selected from lists during the prescription quantification procedure, greater power is obtained by including them on tile patient's record and having the system reference these characteristics each time a new drug is prescribed for that patient and make dosage recommendations according to the known behavior of the selected drug as it applies to the current patient.

eferring to the embodiment illustrated in the drawings, Expires field 104 can be system-calculated field from the entries in Amount field 98 and Dosing field 102, to indicate the dav on which the last dose will be taken. Alternatively, the physicianuser can select, or enter, an expiration date in Expires field 104 for example to coincide with a desired duration of treatment, or next visit, the system can backcalculate refills or the amount dispensed.

Back-calculating prescription quantifiers is useful to coordinate multiple prescriptions to expire on the same day, for the patient's convenience and to reduce potential errors or abuses. Another valuable application of an expiration-controlled prescription is to benefit plan managers, enabling the physician, where appropriate, readily to coordinate prescription amounts to preferred schedules and programs of drug benefit plan managers, for example a ninety-day plan. uch preferred schedules can be system-offered or defaulted, if desired.

Alternatively, if desired, means can be provided for the physician themselves to write or key in the appropriate dosage entries for a

selected drug.

In this preferred embodiment of prescription management system according to the invention, the Drug and Condition fields 88 and 86 are linked together to express the therapeutic objective of the user's prescribing decisions, or the presrribing intent of the prescription , as will be described in more detail with reference to Figures 4 through 11.

As stated above, a preferred objective of the invention is to minimize need for keyed data entry, to minimize information look-up, or preferably to avoid all need for keying, by providing a comprehensive system interfacing with the user through easily operated data entry devices such as employed in pen-based computer devices. To achieve this end, the prescription management screen of Figure 3, is preferably supported by comprehensive, fully adequate, up-to-date databases of drug information that, in a particularly preferred embodiment of the invention, provide a physician user with substantially all available relevant prescribing information on drugs, especially on thoge drugs they write most frequently, which mav be favored with preferential device storage on the user's interface device, for rapid retrieval.

elevant prescribing information on other drugs, written less frequentlv, or not at all by that user is available on the network.

Prescril2tion fulfillment
When drug specification is completed to the physician's satisfaction, Send Rx button 80 is pressed to output the newly created electronic prescription in any desired form such as to print, to local or remote storage or to remote file transfer as an electronic prescription . Tlie electronic prescription can be transmitted across a network for fulfillment by any specified phannacy, for example, the patient's preferred pharmacy or a pharmacy preferred by the patient's drug benefit company for the particular patient's locality. Preferred routing options can be provided for the patient or the drug benefit plan, or both, and the system can default to appropriate options for the patient's benefit plan. outing may be more or less complex and may for example 1 5 split say a one-month prescription to provide a brid e prescription giving the patient
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an immediate one- or two-week supply from a local pharmacy, and sending the balance of the prescription for fulfillment by a lower cost mail order house. If desired, a Bridge Rx button (not shown) may be added to prescription creation screen 39 to perform such a prescription -splitting function.

Patient coml2liance and prescription drug abuse
Ensuring that a patient complies with the terms of a prescribed
treatment, neither neglecting nor overindulging in a prescribed drug
therapy, is a serious problem in health care management. It is difficult
to ensure that out-patients actually ingest the prescribed amounts of
medication at the prescribed intervals. Many mistakes and abuses occur.
The problem is exacerbated when a patient is prescribed a confusing
multiplicity of drugs that may have to be ingested in different amounts
at different times of the day. The present invention enables, and
includes, unique solutions to this problem that greatly facilitate a
patienes abilitv to comply with a simple or complex regimen of
dosages,without costly skilled supervision. In addition, many types of
intentional abuse can be monitored and possibly prevented.

One approach to enhancing patient compliance, according to the invention,
employs a novel dose-scheduling drug package that is readily adaptable to
accommodating and scheduling single or multiple prescription dosages to
help a patient take the right dose of the right drug at the right time,
and will be described in detail hereinbelow.

Another approach is, to some extent, inherent in features of the
prescription management system described herein. Where multiple
physicians accessed by a patient utilize the system described herein,
with common online access to, and I 0 assembly of, a patient's
prescription history record whereby that record provides a current
record of new prescriptions, then a common abuse can be controlled
wherein a patient presents a problem or condition to more than one
physician to obtain multiple prescriptions with a view to indulging in
abusive ingestion or illicit resale.

This problem is especially prevalent with analgesics. Where a physician,
or perhaps 1 5 pharmacist, if the patient's prescription history is
available to the pharmacist, sees a similar current prior prescription
has been issued, they can refuse to duplicate it.

Clearly, regulatory authorities wishing to control such abuses can
further that goal by encouraging widespread, or universal, deployment of
the prescription management system of the invention. Where the system
also provides, for example in the patient's history record, notification
from a pharmacy, or from a drug benefit plan linked to the phannacy, of
fulfillment of a prescription , and that information is available to the
prescriber, for example from the patients' history record, another common
abuse wherein a patient pleads loss of a prescription to obtain a
duplicate, can also be prevented.

Bringing fulfillment information from the pharmacy to the point of care

via the
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patient!s record or other convenient reporting medium, with or without
the intermediary of a drug benefit company linked as a remote source
database, can provide not only a valuable prescription abuse monitoring
parameter but can also be used to enhance compliance with the prescribed
treatment, especially if coupled with an alerting system.

For example, the system may alert a prescriber that the intended
expiration date of a critical prescription has passed without the
prescription having been filled. The prescriber thus becomes aware that
the patient has gone off the medication and can take steps to contact the
patient and alert them to the dangers or problems that may arise.
Alternatively, routine alerts can be passed to administrative personnel
associated with the prescribing health care provider, notifying them of
any unfilled I 0 prescription after a prespecified period of say two
weeks or a month, or prescription expiration, or a shorter period for
more critical medications.

Scheduled dosage drug Dack
A particular benefit the system provides when a patient has multiple
simultaneous prescriptions is an ability to print out a dosing schedule
or better still, to generate a scheduled dosage multi-drug package from
the electronic prescription , for example as shown in Figure 15. Because
the system knows dosage, dosage frequencv and the duration of all
prescriptions, it can report out what pills should be taken at different
times of the day to comply with the requirements of multiple medications.
The information used for such a further report can drive the dispensing
of the drugs of a multi-drug prescription into a novel package which
has multiple labeled or coded compartments for each of a number of dosing
intervals.

Figure 15 shows a scheduled dosage drug pack 182 configured as a daily
pack with the day of the week prominent and the date, patient and doctor
identified. Across
pack 182 run three multi-compartment drug bays 184 each of which can
accommodate up to four different solid drug formulations 184, pills,
capsules, tablets, caplets, or the like and is sealed by a tear strip
having an opening tab 186. Each bay is clearly labeled with a time of day
at which the dosage in each bay 184 should be taken. Vertical zones 188
are dedicated to an individual drug and comprise a header with a drug
name and special instructions (takewith water, after food, and so on) and
a compartment in each bay 184 for each dosage time. To demonstrate the
flexibilitv and dose-organizing power of this novel, pack-based system a
first drug is shown schematically in lefthand zone 188 with thrice-daily
dosing, a second in left central zone 188 with twice-daily dosing and a

third in right central zone 188 with once-a-day dosing. ighthand zone 188 is not used, but could be occupied by a fourth drug, the individual dosages of which are loaded into those individual compartments of ighthand zone 188 that correspond with desired dosage times or intervals.

- Clearlv, modified drug packs 182 embodying the principles of that shown in Figure 15 could be configured for more (or fewer) doses or drugs or for different calendar periods, for example weekly or monthly packs rather than daily. Nor is the card configuration essential, for example, a multi-dnig container could be in strip or roll or book form, or metal foil sheets, with tear or press-out compartments. Dosing errors are common with patients with multiple prescriptions, especially the elderly. There can for example be difficulty in knowing whether a dose has been taken or not. Drug pack 182 solves these problems in a simple inexpensive manner that is prescription controlled to organize multiple doses correctly and can be easily followed by most patients. Individual sealing of doses is hygienic and child- or overdose-resistant.

Daily or weekly cards could be connected together by hinges to make compact concertina or book-like packs supplying a week or a month's prescribed drug requirements.

Variations on tile theme of a scheduled dosage pacl<age will be apparent to those skilled in the art. If desired, the package could be standardized as to tile number of dosage compartments, providing for example, a compartment for every hour, with those compartments lying between desired dosage times being obviously blank or never filled. A valuable feature of such packaging, which could be embodied in a 30 single prescription package, is that by giving the plivsician-prescriber sorne physical control over the circumstances that exist when a patient is supplied with drug therapy for remote administration, the prescriber gains the freedom to adopt time-related dosage variations during the course of therapy,without confusing the patient. In a simple example, scheduled packaging might provide one pill in the morning, one at lunch time, and two at night, in an attempt to maintain blood drug levels through the night.

Other regimens could provide higher initial dosages to build up blood drug levels, followed by lower maintenance dosages. In any such case, the patient simply takes, or is administered, at any given time, whatever dosage or dosages have been packaged into the bav 184 that is appropriately identified by patient, time and date. More subtle or more complex regimens will be apparent to those skilled in the art, for example one drug might be discontinued, and possibly resumed after a suitable interval, while another continues. Another useful technique to be able to administer via the dosage-scheduling pacicage described herein

is to taper down one drug while beginning to administer another, to provide a graduated switchover. Changing anticonvulsant therapies from one drug to another is an example of where this technique may be useful.

Prescriber-controlled dosage scheduling can be included in tile system via an additional window or screen, offering the prescriber selection of the relevant variables, such as time-related dosages, with defaults or preferred selections for what can be system-determined as the most probable or most beneficial choices for the patient being treated, or accord with the patient's formulary's preferences or with the particular prescriber's preferences, pursuant to the principles described herein.

pecific tapering or starting protocols can easily be implemented for outpatients decreasing the requirement for costly skilled supervision.

Dosing Indicator Device
For more needy patients, the time- and date-scheduled drug packaging described herein can be rendered electronically or electro-optically readable, for example with bar-coding or by using transparent compartments, to cooperate with a novel dosing indicator device that a patient could take %%rith them to their home or on their travels.

uch a novel dosing indicator device, as contemplated herein, includes a time-anddate clock and is designed to receive at least one scheduled dosage package, as described herein, and to inspect that package to determine what drug pills, capsules or the like have been removed. In the event that a pill or the like is detected in any bay stamped with a date and time prior to tile date and time clocked by the device, an audible or visual or remote alert, or a combined alert, is triggered. Inspection I 0 sensing is preferably electro-optical and targets individual compartments with a light beam that is reflected or diffused by an individual pill or associated light-modulating tag, or by a bar code stamp or label which is required to be removed %%rith each dosage of any drug. The device can include a movable scanner that advances in relation to a package from one bay 184 1 5 to the next, scanning relevant compartments in the bay, as time passes, or it can comprise an array of photoelectric sensors registering with individual compartments of the package, which are electronically controlled and read in turn, as time passes.
Equivalent sensing systems will be apparent to those skilled in tile art.

A preferred embodiment of dosing indicator device accommodates, within an aesthetically pleasing housing, a multi-bay scheduled dosage package, a time-and-date clock, a time-related sensor to detect the presence of a drug dosage in the bays one or more alerting systems, associated electronics which may include a microprocessor, and a power supply, for

example, a battery, ac connector or remote drawdown source, or the like.

uch a dosing indicator device can be embodied as a motor-driven single- or multidrug dosage dispenser which, for example, can house a tape, or strip-like and preferably rolled, scheduled dosage package, having a time line along the roll, and 30 advances individual bays 184 containing one or more dosages for a given dosage
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time, and presents a single bav 184 (containing one or more dosages) for external deliverv and removal (for example by tearing) by the patient, or patient's aid, in timed relationship to the dosage tirne (a half hour before, perhaps) and triggers one or more alerts if the bay 184 is not removed (a half hour after, perhaps).

Preferably, each bay is accompanied by written information as to the patient, time and date, each drug, and any relevant dosing instructions. The individual compartments of such a removable bay cannot readily be sensed for the presence of individual pills. Clearly a sensor is required for the presence of an externally exposed I 0 bay. The system assumes that the pills in a removed bay will be ingested, but this assumption may be wrong on occasion. More ri orous patient compliance mav be
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exacted by including in, or in association with tile device, a receptacle for an emptied bay 184 and triggering alert means if such emptied bay is not received within a specified time interval. Emptied bays can be retainedwithin tile receptacle. To deter deceit of the receptacle it can read a time and date stamp, or other unique identifier on bay 184.

A multipatient version of the drug dosage dispenser described herein can also be provided for inpatient use in medical or health care facilities, especially hospitals and clinics. uch a multipatient version could comprise a central dispensing station, located for example at a nurse's station. The dispensing station can have multiple ports, preferably identified with bed locations and bed-occupants' names, whereby scheduled drug dosages for each bed-occupant patient are dispensed at scheduled dosage intervals, if desired with appropriate alerts or indicators. Nursing or other staff can readily remove and administer the correct drug dosages for multiple patients, possibly on a single round, or at specific times of the day.

Drug contraindications
A further valuable feature of the novel prescription management system described herein is an ability to review a completed prescription for contraindications, or relative contraindications, such as patient allergies to the prescribed drug and such as possible drug-to-drug interactions with other drugs the patient has previously been prescribed.

Contraindications may be clear-cut, for example, penicillin must not be selected for penicillin-allergic patients, whereas relative contraindications are less decisive and may be overridden by the prescriber in appropriate circumstances, for example an N AID (non-steroidal anti-inflammatorv drug) may be a preferred choice, in the prescriber's judgment for a patient with peptic ulcer disease, in spite of
the attendant risk of ??
The system can also screen or review for other possible unintended adverse outcomes to the prescribed therapy, or for special precautions regarding a prescribed drug's use.

Preferably, the system alerts the physician-user at tile point-of-care if they prescribe an offending agent, and provides an alert and an opportunity to amend the 5 prescription before dispatching it for fulfillment. Processing to screen for interactions may occur on the user's point-of-care device or on tile]lost computer facility or remote computer system, or may be delegated elsewhere by the host computer facility, and reported back to tile physician, online as an integral function of the prescription process. Alternatively, interaction screening may be run on pharmacyrelated svstems, and notification of problems can be sent immediately to the user's point-of-care device using e-mail or using procedures within the prescription management application of the invention.

An allergies review can be conducted by checking system-stored known allergies of patient Mary Harrington against known pharmacoldnetics and pharmacodynamics of the newly prescribed drug, entered in prescribing zone 44, for any of those allergies. Marv Harrington's allergy information is preferably an adjunct to her patient record and is downloaded to tile user device from host computer facility when Mary Harrington is selected from the patient selection screen of Figure 2. Drug 30 allergenic proclivities are also downloaded from one or another remote database emploving the host computer facility, under supervision of the inventive prescription management system, but preferably at a later point in the procedure, such as when a particular drug is selected for posting to prescribing zone 44.

Alternatively, the requisite information can be downloaded when the allergy review is conducted. uch allergy screening can alternatively be effected when a new drug is posted to Drug field 88. Either wav, a positive system finding, indicating a risk of allergic reaction to the newly selected drug can activate a visual indicator or warning, for example, Allergies button 52 may blink and, if desired, an audible warning may I 0 sound alerting tile physician to reconsider their selection. Alternatively, or additionaliv, an alert screen can tell the

physician of an allergy if an attempt is made to prescribe an offending drug. uch alerts can be used to notify the physician of drug interactions, treatment warnings or can alert them to non-compliance with formularv recommendations, for example to the use of an unnecessarily expensive drug, and mav be accompanied by suggestions for more appropriate alternative therapies.

Equivalent procedures can alert to possible drug interactions and contraindications, referring to the patient's prescription history for possible active or recently expired prescriptions that may interact with a newly prescribed drug, and for other patient data relevant to the drug's behavior in that patient. Alternatively, the such a review for possible undesired aspects of the drug's perfon-nance on the patient is made upon activating Send Rx button 80.

Electronic 12rescription transmission
Activation of Send Rx button 80 can provide a drop-down menu of choices including H end this prescription " and "Add prescriptions prior to sending in a batch".

A preferred embodiment of the invention includes a capability whereby a completed
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prescription is transmitted across one or more data networks for fulfillment and record updating in a wired or more conveniently, for mobile professionals, a wireless broadcast. Preferably, where new information is generated in the prescription creation process, relevant remote source databases (which may be proprietary) are updated with appropriate components of the new information and such updates are effected with proper controls to ensure data integrity, confidentiality and authenticity. Using the system as described herein, all transactions generate an audit trail and are authorized or preauthorized by the patient.
Because of the currently substantial cost of air time, batch transmission is highly I 0 desirable. Accordingly, system defaults encourage the physician to elect batch transmission of multiple prescriptions for an individual patient, although in keeping with the principle of not imposing constraints on a physician, the system does not mandate such batch transmission. Executing a " end Prescription " function outputs the prescription for fulfillment in any desired fon-n, posts the completed new 1 5 prescription to the prescription History zone 43 in the center of the screen, and outputs the new prescription from the user's station to update a control system or remote database, as desired. Prescriptions can be electronically transmitted to a pharmacy or pharmacy.management system for fulfillment, or printed on paper for paper-based fulfillment by hand delivery or fax.

The inventive prescription management system embodiment disclosed herein is designed flexibly to facilitate a physician's prescribing activities, to place helpful information at their fingertips and reduce manual loolc-up chores, while avoiding any authoritarian direction, mandate or constraint upon a Physician's professional activities or judgement. Tlius, while the system may attempt to provide intelligent options and exhaustive selection lists, options such as "other" are always available to permit the prescriber complete freedom of choice, whether or not their choice is known to system-available databases.

Optional system enhancements provide for enrichment of external communications,
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for example prescriptions and e-mail with what may be termed "electronic ink" messages generated at the user device. "Electronic inlc." refers to notes or messages appended to external communications, or transactions in the form of free text or voice annotations for non-structured instructions, and the like. Voice annotation is particularly convenient, as well as possibly constituting unique user-identification and some currently available low form factor user devices incorporate a microphone, facilitating voice annotation.

Toward the end of prescribing flexibility, to avoid being second-guessed by physician I 0 users, and to command their respect and loyalty, the system should have access to, and provide to its users fully comprehensive dnig and patient information so far as
this is available. Comprehensive, accurate and complete drug and patient information are equally important for effective prescribing. It follows that the drug and patient information source databases froin which the prescription management system draws, must be maintained tip to date, by appropriate network services.

It is the normal, challenging nature of highly qualifled professionals that those with the latest news, such as new drug releases and approvals, will want immediately to test the svstem for currency with the news.

The unique source-oriented information retrieval and updating system described herein provides preferred means for supporting the prescription management system of this invention with an adequate infra-structure of data-retrieval networks supplying a comprehensive array of up-to-date prescribing infon-nation and patientrelated data to the point-of-care. Other suitable infon-nation data retrieval and updating systems will be apparent to those skilled in the art and can be linked to the system of the present invention to provide allergy and interaction alerts, formulary changes, new drug approvals, and to lock

out or warn against, the prescribing of inappropriate or recalled drugs.

Drug and condition selection
Novel drug selection methods pursuant to the invention will now be
described with reference to Figures 4 to I 1. The condition list
selection screen shown in Figure 4 appears upon activation of Condition
field 86 in the prescription management screen of Figure 3, to enable a
prescriber to approach selection of a treatment drug by first specifying
a diagnosed condition. Alternatively, a drug may be directly specified by
drug name by activating Drug field 88, as will be described in connection
with Figure 9, after which the prescriber selects a condition to specify
the purpose of the
therapy. uch condition or dru selection screens can be opened by similar
9 I
condition or drug buttons in anv other relevant screen or application,
for instance in a patient encounter screen where the drug selection
routines now to be described with reference to Figures 4 to I I can be
used to assist a physician to select or review treatment objectives in a
computer-assisted patient encounter.

1 5 Condition list selection
The condition list-selection screen of Figure 4, provides a preliminary
selection of a suitable condition list from which a physician user can
work to select a drug. As shown, the screen comprises a Select Condition
List title I IO and a Condition List display header 1 12 beneath which
the names of Condition Lists 1 14 are grouped in a left-hand column. A
right-hand column beneath header I 1 2 displays the conditions I 1 6 of
whichever condition list 1 14 is highlighted, or otherwise selected.
In this case the user's personal condition list 1 14 has been highlighted
and may be seen to comprise a short list of commonly occurring problems
that, for example, a general practitioner might encounter.

Multiple different Condition Lists 1 14 are available in this embodiment
to provide a range of choices to physicians, and six are shown, by way of
example. Three of these lists 1 14 classifv conditions broadly by
diagnosis (Dx) and comprise a systemmaintained Dx"Personal list 1 14, an
alphabetically organized Dx-Alphabetic list 30 114 of all conditions in
the svstem and a Dx-Category list I 1 4. Dx-Category list 14 lists
conditions by broad therapeutic category such as cardiovascular, GI or
dermatology. A fourth condition, problem or diagnosis list, Dx-Patient
list 1 14 lists previously exhibited conditions or problems of the
selected patient, in this case, Mary
Harrington. Dx-Patient list 1 14 is system maintained (and manually
supplementable) and changes according to the patient selected in the
patientselection screen of Figure 2. Dx-Personal list 1 14 is also system
maintained (and manually supplementable) and changes according to which

prescriber signs on.

Preferablv, the system includes frequency counters to track the
conditions the user I 0 encounters with time, and the counts obtained are
used autornatical l v to maintain or generate a Dx-Personal list 1 14 for
the user, which more closely portrays patterns of conditions encountered
in the user's practice as time goes by. Base periods for reporting usage
may be varied, or user selected, to list conditions encountered by
frequency in, for example, the last year, the last five years, or
perhaps, the last three 1 5 months. Also, a default can be included to
highlight a selected patient's last active condition or conditions as a
first-line choice.

Preferably, any time a new diagnosis is inade, the new condition
encountered is placed in the user's Dx-Personal list 1 14 and any time a
drug is chosen it is placed in a personal drug list for the user. The
firsz tit-ne either a condition or a drug is selected, it is added to a
user profile stored on the network, for example, at the host computer
facility.

In addition, a physician-user can manually maintain one or more custom
lists, DxCustom I list 1 14 and Dx-Custom. 2 list 1 14, for their own
preferred short lists of conditions being, for example, conditions
appropriate to their specialty that the individual physician frequently
encounters for treatment. Alternatively, libraries of specialty lists may
be made available from which the user selects one or two lists for their
personal use. uch custom lists 1 14 may be associated with different user
activities, for example, Dx-Custom I could be used at a hospital where
the user is an attending physician, while Dx"Custorn 2 is used at a pain
clinic where the user is a visiting physician. The various condition
lists I 1 4 provide alternative pathways to drug selection that a
physician may use as an aid to deciding upon a course of treatment.
Different pathways may suit different clinical circumstances or
prescribers. Availability of alternative routes to relevant drugs may
enable a physician to find improved treatments, and increase their range
of choices, and may lead to new solutions to difficult prescribing
situations.

The condition list selection screen shown in Figure 4 is a gateway to
other condition and drug selection screens. As an alternative for
quicker selection, a preferred - condition list (typically a Dx-Personal
list 1 14) could be set as a default with other
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condition lists 1 14 being reached via a Change Condition List button
(not shovm).

Any or all condition lists 1 14 can be automatically supplemented or maintained by 1 5 the system as it receives data in the course of processing numerous prescriptions for one or more physician users. In addition to supplementation with user-originating data, preferred embodiments maintain user profiles on a host computer facility which continually refreshes the data at tile user's device so that the user can use any device or share a device with other users.

Condition selection
In the Select Condition screen of Figure 5, tile patient condition I 1 6 in the Dx Personal category shown comprise generalized groups of disease, some serious like diabetes and pneumonia, and others less so, for example rhinitis or sinusitis. More complex embodiments than the one shown here may categorize conditions into as many as four or five different columns of subcategories of condition according to
disease pathology, therapy, personal knowledge and so on. uch condition categorization, as a preliminary to dnig listing, provides a very powerful tool for physicians to view their prescribing options on screen and to organize them.

Organization of dru s bv lists of effectively treated patient conditions enables a user
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intelligently to access a large bodv of drug data selections. This approach provides multiple mapping so that the user can find a suitable drug or selection of drugs via different pathways according to their preferredwork methods.

Different pathways to a drug via conditions organized in other ways, notably by body system, are illustrated in Figure 8, described hereinbelow. Direct pathways of drug selection using drug lists are illustrated with reference to Figures 9 and IO, described hereinbelow.

In the example shown in Figure 5, the user-physician has highlighted and selected a patient condition I 1 6, namely, peptic ulcer disease (PUD)/gastritis, displaying, in the next right-hand column (see Figure 6), a short, systern-generated list of drugs known to be therapeutically indicated for PUD/Gastritis and which may be suitable for prescription or to have been prescribed in the past by that user for treating these 15 conditions. The presence of the user's previously prescribed drugs, which may not necessarily appear on third parties' lists, helps personalize the list to the user.

eferring to Figure 6, now that a condition, PUD/Gastritis, has been selected, a new screen title, Select Drug I I 1, appears and selection of a drug to treat this condition proceeds. To aid the selection, a

condition-specific, formulary drug list I 1 8 is displayed in the next right-hand column of the Select Condition screen of Figure 6 under Formulary Drug header 120. Alternativelv, a physician's personal list of drugs may be displayed with fon-nulary drugs highlighted. If desired, relative cost information can be included or alternative dru s may be ranked by preference of the

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formulary manager.

Formulary Drugs are those listed by a drug formulary specified by, or relevant to, the

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patient, in this case, Mary Harrington. The drug formulary may be generated by a prescription benefits management company and is a key ingredient in a svstem for reducing overall prescription costs bv using volume purchasing to get preferred pricing on selected drugs.

A major problem in fulfilling the cost-control objectives of a managed care organization is that of informing a prescribing physician as to which drugs are in the formulary for a given patient. Noting that there are many different formularies it is quite impractical for the average physician to keep referencing different formularies for every patient every time thev write a prescription . The aspect of the invention shown in Figures 6 through I I helps solve this problem by providing computer access of remote databases containing the information and by presenting available I 0 formulary drugs in a form which is easy for a physician to use, reference and prescribe

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without enforcing physician compliance with a fori-nularv's treatment guidelines and attempting to restrict a physician's exercise of their professional judgment.

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To the contrary, the system of this invention is designed to empower a physician to 1 5 make informed choices at the point of care. The system fosters quality, cost-effective prescribing. Physicians do not have to attempt to remember drug formularies and forrnularies may be changed with instant effect on all users without having physicians relearn the formularv. Where formularv infonnation is called across a data-retrieval network, each time it is required, in accordance with preferred embodiments of the invention, from a remote source database, updates are automaticallv posted across the network.

Nonformulary drugs may be substantially more expensive than forinulary drugs, or may not be covered by the patient's dnig benefits plan, and may require out-ofpocket payments by the patient which circumstance may cause

administrative problems to the physician and be a burden to the patient. Worse still, the patient may not have the prescription filled.

By including pharmacy-derived prescription fulfillment information, a patient prescription history can indicate whether a patient actually received a medication.

The physician can be alerted (bv e-mail) if a patient has not filled a prescription for a
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critical medication, for example LA IX (Hoechst), prescribed for hy
. pertension,
enabling a follow-up with the patient to be initiated.

Where formulary drugs are professionally acceptable to the physician and of equivalent therapeutic effect to non-formulary drugs, failure to use them is clearly undesirable. This problem is overcome by the present invention. If the physician is satisfied with the formulary drugs offered by the prescription management system of this embodiment, anyone may be selected and automatically posted to the novel prescriptiondescribedhereinaswillbedescribed.

Prescribing non-formulary drugs
hould the physician know, for example, that cimetidine and ranitidine, drugs in a similar class, have been tried and found ineffective and that the condition is well beyond these first line treatments, so that none of the formulary drugs is suitable, then the physician can select Other, which selection displays a nonformulary drug list 122, under nonfonnulating drug header 124, as shown in Figure 7. In this case, the physician selects Sucralfate as being a non-fon-nulary drug in a different chemical category and having somewhat different therapeutic properties from those previously applied to treatment of this patient's symptorns.

Having made the decision to select ticralfate, the physician is informed bv the system display shown in Figure 7 that sucralfate is a nonformulary drug not on patient Mary Harrington's prescription benefit management company's schedule.

With this timely notification in hand, the doctor can, if appropriate, consult with a patient, explain the reasons for his or her drug selection and gain the patient!s agreement to assuming the cost of the prescription , or obtain authorization from the plan to cover the cost of this prescription for this exceptional case. Physicians manifesting increasing comp liance flowing from use of a prescription management system according to this invention can expect ready approval of a

non-formulary drug on a justified exceptional basis.

By tying a diagnosed condition to a prescribed drug and requiring a condition to be recorded as a treatment objective before a prescription is fulfilled, new drug formularies can be created where prescribing of a drug is qualified according to the condition treated. For example, an expensive drug like captopril may be a first-line formulary choice for an acute condition such as congestive heart failure, but not a first-line choice, or may even be excluded as non-formulary, if prescribed for a chronic condition such as hy
pertension.

In practice, after the system learns the user's preferences, most condition and drug selections will be quickly made from the user's preferred or custom lists or from historically derived patient lists of previously encountered conditions, or previously prescribed drugs. The system adapts to the prescribing user to enable rapid creation of routine prescriptions. A minority of situations may call for less obvious therapies or therapies with which the physician has little or no experience. Physicians tend to be most reluctant to prescribe new drugs. esponsible physicians will usually scrutinize a great deal of relevant infori-nation before prescribing a drug for the first time. This effort is captured by the systeinwhich enables a prescriber to have quick access to their prior experience and confine their drug selections to drugs they have used previously and which were satisfactorv. (A physician can of course edit their personal list to remove dnigs; that proved unsatisfactory for some reason or another, whether therapeutic or not, or they can be removed automatically based on
decreasing frequency of use.)
In other circumstances a physician will need to select a drug with which they have little or no experience. Here, when it is most needed, the system provides major support and reassurance, presenting several different pathways to appropriate solutions enabling online access to the latest available scientific, clinical and commercial information about a new drug as well as screening for complications.

The ability to offer dnig detailing at the point of need for new drug information can be used to attract revenue from phan-naceutical companies, managed care companies or others, and is especially useful in decreasing the barriers to switching to first-time use of a drug. The system-provided prescribing information resources that are brought to the point of care are also valuable in enabling a physician to make quick therapeutic substitutions.

The drug selection screen shown in Figure 8 offers, by way of example, one route to selecting a new drug not on the prescriber's short lists.

Here, selection is condition driven and proceeds with the selection of a condition list I 1 4, Dx by Body System or Dx by Therapeutic Class, and then locating a drug to treat that condition; or altemativelv, by directly selecting a drug via drug lists 1 15 Rx by Therapeutic Class or Rx by Alpha. Displayed in Figure 8, reading across the columns frorn left to right, are a list of body systems I 1 7 from which the prescriber has selected Musculo1 5 skeletal. In the next right column the system displays a list of conditions I 1 6 that might be displayed by the musculo-skeletal system, of which nine are listed by way of illustration. From these nine the prescriber has selected Osteoarthritis.

Ostcoarthritis is posted to Condition field 86 in prescribing zone 44 of prescription creation screen 39 (Figure 3).

With a condition specified, selection proceeds to the choosing of a drug to treat the condition of osteoarthritis. Drug selection proceeds through a preliminary selection of drug category, from a list of drug categories I 1 9 in the next column to the light, enabling the prescriber to choose their therapeutic approach, in this case, as between employing an analgesic, a narcotic, a N AID (non-steroidal anti-inflammatory drug) or a salicylate. A NSAID is chosen, generating an extensive list of drugs 121 in the right most column in Figure 8, from which the prescriber can make their final selection which will be posted to Drug field 88 in the prescription creation screen 39 (Fig. 3).

The complexity of the prescribing process is graphically illustrated in Figure 8. Even after narrowing the field down to a specific class of drugs, N AID , for treating a particular symptom, osteoarthritis, there are still of the order of fiftV drugs from which the prescriber makes a final selection.

Direct drug selection
Prescribers often know what drug they want to prescribe and will wish to access it very quickly, and may not use the system if they are unable to do so. This goal can IO be reached with user-adaptive personal drug lists organized to default to a prescriber's
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preferred choices, as described herein.
One preferred user-adaptive approach to providing a quick-prescribing pathway to a prescription is for the system to process the user's personal drug list, to highlight, or 1 5 short-list or otherwise present those drugs on the personal list that are appropriate therapy for any of the patient's active conditions, and preferably also, that are on the patient's formulary.

eferring to Figure 9, an alternative direct drug-specification pathway

commences, reading from left to right, with selection of drug -list II 5
Rx by Therapeutic Class.

From a list of perhaps fifty to one hundred drug categories 1 19 which
appears in the next right hand column, the prescriber has picked
Diuretics, generating an even longer list of diuretic drugs 121 from
which the prescriber has picked Dyazide (trademark, mith Kline Beecham).
The system now calls for entry of a condition, in this case
"hypertension". The extent of the lists of drug categories I 1 9 and
diuretics 12 1, again illustrates the bewildering array of drug
selectionsMth which a prescriber is confronted. An otherwise uncertain or
overlv conservative decision-making process can be rendered efficient,
reliable and manageable by a prescription management system according
to the invention.
The selection program illustrated in Figure IO provides a variety of
pathways for direct drug selection via five drug lists 1 15, a personal,
an alphabetic, a category list and two custom lists, analogous to
condition lists 1 14. Here the user has selected RxaAlphabetic list 1 1 5
and the system has displayed a portion of a long, scrollable list of
drugs 121 in the next column. This approach can quickly locate a target
drug when the physician knows it by name. Here Cefixime has been selected
and the system calls for, and requires, tile prescriber to enter a
condition before proceeding to quantification of the prescription . In
the next column the system lists conditions that the user has previousiv
treated with Cefixime, highlighting the most recent I 0 condition so
treated, or the system may display a previous condition of this patient
that was treated with cefixime, not necessarily bv tile current user. If
the physician wishes to attack some other condition with cefixime, such
other condition may be selected from the last righthand column, activated
by "other".

The diversity of conditions treatable with cefixime illustrates tile
potential for 5 outcome studies based upon widespread use of systems
according to the invention to refine definitions of the therapeutic scope
of individual therapeutic agents by collecting data on effective new
applications and oil precautions, interactions and side effects.
Some advantages of condition-specified drug prescribin
Being abundantly served at the point of care with relevant prescribing
information at the critical moment of decision, the physician can
eliminate manv subsequent problems or difficulties which may lead to
unnecessary paperwork, or surprised, annoyed or non- compliant patients,
and to unnecessary phone calls between pharmacist and physician when a
patient learns only at the phan-nacy that their prescription is
non-formulary. The system can eliminate much unnecessary "phone tag"
between pharmacies and physicians. Improved physician and patient
compliance with preferred guidelines will reduce tile cost of care and

increase the quality of care.

The availability, by means of the invention, of vital drug selection information, categorized by therapeutic condition and denoted as formulary or not,for the patient in question, rapidly assembled, preferablv from remote source data, and conveniently presented to a physician for flexible use in their own personal work flow, greatly enhances prescribing practices, fosters cost containment and eases the administrative burdens that fall on heavily prescribing physicians. It enables informed choice at the point of care leading to a decrease in adverse outcomes of therapeutic choices.

Naturally the prescription management system of the invention can provide a variety of printed reports and other data outputs of any facet of the described operations. In I 0 some cases, these reports can be enhanced to provide entirely new products for example a dosing schedule such as that described with reference to Figure 15, and shipping schedules or split prescriptions divided according to suppliers requirements.

Current and historical reports can, subject to the access controls described herein, be 1 5 patient-specific, prescriber-specific or organization-specific and can be aggregated across various groups, pools, geographical regions, conditions, drugs, or time periods or combinations of any of the foregoing to provide a valuable data resource to health care providers, patients, managed care organizations, government agencies and others.

Further to enhance the prescribing decision process, additional features can be included on screens such as Figure 7, for example drug pricing infon-nation, employing actual wholesale or retail pricing, or comparative pricing or on another manner of drug pricing or grouping, such as a comparative scale or price rating system, or relative pricing based on actual prescription benefit management company contracts. uch pricing information can greatly influence M.D. decision-making, improving formulary compliance and reducing overall drug costs, without restricting a physician's choices.

A powerful optional feature of the invention is shown in exemplary fashion by the drug evaluation screen depicted in Figure I 1. After a physician selects a drug from one of the screens of Figures 7 to IO, the system can optionally scan a drug preference database of preferred drug treatments for an evaluation of the merits of the selected drug in treating the condition. The drug preference database may be remote and may be maintained, for example, by a managed care organization, HMO, or prescription benefits management company. As the Figure I I example shows (which example employs different condition and drug selections from

those used in Figures 6 and 7) one possible result of the database scan may be an on-screen report with an alert message, in header 126 advising tile physician that tile selected drug is "Not a first line drug" for treating the selected condition. As a helpful suggestion to the physician the system can also offer alternative drugs, from listings in the drug preference database, as being more meritorious for the treatment of the condition in question (pursuant to the maintainin benefit companys standards or, preferably, to
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objective literature reports).

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To this end, the drug selection evaluation screen of Figure I I comprises an explanatory box 128 elucidating header 126; an alternative drug selection menu 130; and at the bottom of the screen, three action buttons; for example, Tx Guidelines 132 to access treatment information about the alternative drug highlighted in menu 130; a confirm button 134 to post the physician's original drug selection, in this case "Cefixime" and to return to prescription creation screen 39; and a cancel button 136 which returns the user to the drug-selection of Figure 7.

The treatment infon-nation available via Tx Guidelines button 132 may include a literature reference supporting the system's finding that Cefixime is not a preferred first line agent for treatment of the selected condition, otitis media. Optionally there mav be a selection on a drop-down menu from the Tx Guidelines button 132 enabling a physician, without further effort to have a copy of such a study sent to them. In a further optional embodiment, Tx Guidelines button 132 can provide the 30 user with an access point to full disclosure and prescribing information on the drug. Available treatment guidelines infon-nation can include details of the particular conditions for which a system suggested alternative drug has been found effective, adverse conditions, preferred dosages and administration routes, literature sources and so on. This aspect of the inventive system provides a simple, nonintrusive technique for bringing new drug information to physicians at a critical moment of need, when creating a prescription .

Although described as a self-contained system, it will be appreciated that functions such as the identification and listing of drugs via conditions treated, and patient I 0 prescription histories will have value in other systems, for example, patient encounter management systems, and may be accessed directly from such systems via a prescribing information button.

As well as compensating for error or lack of information on the

physician-user's part, 1 5 the prescription review system exemplified
in Figure I I has great value as an educational tool. Physicians can be
subtly trained to improve their drug selection behavior. By using the
system aggressively and exploring its information resources, as they are
encouraged to do by the system's prompts and alerts, physician
prescribers effective l v receive education and training at the point of
care. Improvements in drug therapy are subtle and complex and it is often
difficult, even for the most conscientious of physicians, to be abreast
of developments in any more than one narrow field of medicine. It is just
as difficult for purveyors of new drugs to break in to a physician's
packed work schedule to educate them as to the merits of a valuable new
drug.

More than one alternative drug may be offered. Also in an optional
embodiment not shown, the physician user may choose to display a screen
of drug information regarding the alternative drug or any other drug.
After confirming a drug selection the system can review the patient's
history in relation to the selected dru and alert
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the physician to any relevant allergies, one-on-one drug interactions or,
if appropriate, multiple drug interactions.

Often, when new drug information is presented, a physician is unable to
consider it, yet when the information is needed, or could be used, for
example at the point-ofcare, when creating a prescription , valuable new
drug information may be unavailable or forgotten. This invention solves
that problem by presenting new drug information in a timelv manner at the
moment when it is most needed and a physician is most interested in
considering it, namely at the time of writing a prescription . It gives
a benefit management company the opportunity to influence a physician's
choice at I 0 the most influential moment, during the prescribing
decision.

User-adaptive drug formulaI3@ compliance
Conventional formulary guidelines specify one or more substantial lists
of preferred drug therapies. Many of these drugs will be unfamiliar to
most prescribers whowill 1 5 therefore be reluctant to prescribe them.
Natural professional prudence makes most physicians extremely cautious
about specifying powerful agents for therapeutic goals when they have
little or no prior experiencewith the agents but will be responsible for
the outcome of the treatment.

The system of the invention can provide a novel approach to drug
fon-nulary management whereby prescriber-centric fon-nularies can be
established. By means of the system, drug formulary guidelines
effectively adapt to the user's prescribing patterns or can be followed

effortlessly by the prescriber. This desirable prescribercentricity can be obtained- by giving priority to the prescriber's personal or custom lists or, better still if they are a subset of these, to the patient's history lists, and system-identifying patient-formulary preferences on those lists for easy Final picking by the prescriber. Where the prescriber is selecting a drug providing effective therapy for a just-specified condition, the above procedure may often clearly identify a single drug meeting all requirements or may result in a short list of a very small number of drugs for Final selection. Where no drug is listed as meeting all requirements, the system may so alert the user and suggest formulary drugs not on the doctor-specific lists or ask the user whether thev wish to review appropriate non-formulary drugs from their personal or custom lists.

Patient's prescription histo
Figure 12 shows a prior prescription infon-nation screen which can be displayed by double clicking the prescription display line or activating RX History button 54 in a screen zone such as prescription history zone 43 of prescription creation screen 39 1 0 shown in Figure 3. The embodiment of screen shown in Figure 12 provides a simple passive information display, comprising an information box 138, a close button 140 and a scroll bar 142 for scrollin or browsing a library of prescription histories. The
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displayed prior prescription infon-nation in box 138 comprises, for the selected prescription , the condition for which the dnig was prescribed, the drug name, date of 1 5 prescription , dates of any renewals and the name, phone number and any other appropriate identification of the prescribing physician, in this case it is the user physician, and any other useful details that may not be strictIV prescribing information, including appended free text, voice annotations or other electronic ink.

Where an "N" indication appears in the Mine column 76 on the prescription history line in Figure 3, the name of another physician who authored the relevant prescription will appear in Figure 12.

In addition to conveniently presenting useful historical prescription -related details, powerful optional features, for example, direct E-Mail communication with the physician whose name is displayed (or with some other physician) can be activated from the prescription infon-nation screen of Figure 12 or other suitable screen, can be included in the prescription management svstem of the invention. uch options enable physicians to send an inquiry to, and perhaps retrieve relevant records directly from another physician such as a previous prescriber to the patient, or a referring physician. The invention facilitates the execution of such infon-nation transports during the user-physician's

encounter with their patient. The screen of Figure 12 could additionally have an Auto Dial button and be linked to other modes of communication to facilitate a direct connection to the physician of interest.

Additional options include a display of historical dosage infon-nation and an ability to page through all prior prescriptions or all prescriptions for a given patient, a given prescriber, a given condition, a given therapeutic class, and so on, recapping some of the functionality of the Figure 3 prescription creation screen 39.

A further optional feature of the invention is shown in the patient problem or condition screen of Figure 13, openable, for example, from Problem button 50, - Figure 3, which tracks, as indicated by the field headers 144-156 extending across the screen, a history of the patient's problems and records diagnostic determinations regarding individual problems. in particular, the system captures information regarding the date when a new problem first becomes active and when it is 1 5 "deactivated". These dates are associated with the name of a physician user, and thence with a patient encounter and can be regarded as authentic diagnostic determinations capable of being substantiated from the physician's office records.

Additional information screens, detailing, for example laboratory or other diagnostic data, or relevant personal patient characteristics, for example height and weight, can be linked to problems as they arewith dnigs.

By processing such reliable base data, combined with historical prescription data associating a patient problem, or treatment category, or treatment objective, with a prescribed drug routine, valuable new information and outcome studies can be generated. For example, the duration of problems in relation to particular treatments can easilv be calculated.

Using the Figure 13 screen the system user, or the system, labels a problem.or condition as new in New field 144; describes the nature of the problem in Problem field 146 from a condition list (not shown) such as condition list 1 14 shown in Figure 4; selects a "Y" or "N" flag in Act field 148 to show the status of the condition as active or not; inserts the name of the physician adding the problem to the list in Diagnosing Physician field 150 (which the system will default to the current user); inserts the date the problem was added in Date field 152; inserts the name of the physician determining the problem is resolved or no longer active in Resolving Physician field 154; and inserts the date of resolution in Date field 156. Thus changes to the patient record are stamped with the name and date of the responsible physician to provide an

audit trail. A physician identifier can be added if desired.

I 0 Problems that no longer manifest themselves to the patient or physician can be indicated as not active in Act field 148. The problem list can be sorted by -header selection and preferably presents active problems at the top of the list by default.

uch a system-maintained problem list provides ail easy and convenient reference to 1 5 the patient's history of conditions or problems and of the duration and currency of such problems and constitutes a valuable case management tool for physicians. The problem list is automatically supplemented during the prescribing process with the latest prescriber's latest observations and diagnoses, as indicated by selection of one or more conditions for posting to a new prescription .

Where a patient complains of an old problem a quick prescription creation routine comprises selecting the problem from the Dx-Patient list 1 14, then selecting a drug from a system-generated pick list of drugs providing appropriate therapy for that condition. The pick list is preferably drawn frorn the doctoes personal list and is either compliant with the patient's formulary guidelines, or indicates those guidelines, for example by inverse video, highlighting or the lilre, and also includes a selection of "other" to access drugs not on the prescriber's personal list. tich a quick prescription routine enables the most routine situations to be promptly handled, yet permits the physician to expand their prescribing horizons and does not merely require selection of the same drug as was used previously. Quick treatment substitutions are made possible by the system's-presentation of available alternative therapies enabling the
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scnr)er easily to see what alternatives are available and to explore those with which they are unfamiliar.

Also the problems or conditions on this list can be automatically posted to a patient problem list 1 14 to appear as an additional "Dx" list in screens such as those shown in Figures 4- 1 0, to provide quick selection or review of a patient's historical conditions. Preferably, such a Dx-Patient list I 1 4 changes autornatically when another patient is selected.

I 0 As various system-using physicians, laboratories and the like encounter the patient or provide services to the patient, they become original sources for new record elements memorializing their encounter with the patient or the patient's attributes. The patient's history accumulates, and the system compiles, on demand, a cumulative virtual patient record including all newly created record elements. This current

1 5 patient history record is promptly available to any authorized physician user on the network. In an ideal world, all relevant encounters are captured so that the patient's record is comprehensive or complete.

The value to a patient's care givers, of an instantly available, comprehensive patient record cumulatively reflecting all current and recent medications and conditions, is immense. Its availability to emergency personnel may be life saving.

The problem list screen of Figure 13 is accessed from prescription creation screen 39 (Figure 3) by pressing button 50. electing an OK button 158 or Cancel button 160, the problem list returns to prescription creation screen 39 (Figure 3). Change Status button toggles the highlighted Act entry between "Y' and "N", and records a date and physician namewith any status change. Add button 164 enables a physician user to add a new condition to the list, using condition selection pick lists, as previously described. This routine may be used to note problems for which there is no specific prescription given, e.g. obesity or senile dementia.

Where the inventive prescription management system is applied to statistical data collection for outcome studies, it is preferable to supplement the patient record with a range of relevant personnel data, to the extent that this is available, for example drug abuse behavior, smoking and habitual eating or drinking behavior, dietary habits, marital and family status, pregnancies, ethnicity, environmental factors, and so on. The system provides an excellent means for tracking these factors and their changes as they may pertain to an individual's health. For example, data fields could be added to record any of the foregoing data and the data could be updated by medical or administrative personnel in preparation for a patient-physician encounter.

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Of particular significance to outcome studies will be death certificate information, and preferably this information is added to the patient problem record of Figure 13, as appropriate.

1 5 More complex embodiments of the invention can integrate applications for prescription management with equivalent applications for diagnostic tests, laboratory analyses, and radiological studies to provide a more comprehensive patient history viewable in multiple screens. Of particular value in such an integrated presentation are laboratory results providing drug dosing levels, renal and liver function tests that provide important indications as to appropriate dosing, and so on.

Figure 14 shows a manually maintainable problem record maintenance screen, for physician use, which can be accessed for example from the Doctor's lists button 24 in the system entry screen of Figure 1. This

screen enables a doctor or physician manually to maintain their own personal customized prescription , diagnosis, allergy or other useful lists, to supplement the automatically maintained system lists. If desired, problems the doctor's patients have experienced previously can be systemadded to the list, for example when a patient is selected. These personalized lists or profiles are posted to the network where the system can retrieve them to any user interface device via a host computer facility, subject to appropriate password protection or the like. elying upon such centrally stored personalized profile files,
the system can present a customized, personal appearance, with familiar configurations, attuned to the user's work habits, at any geographical location from which the network can be accessed.

The problem record maintenance screen of Figure 14 comprises a Problem List box 166, a List Type box 168 and a Problems box 170 displaying a comprehensive, or preferably exhaustive list of problems which can be selected and transferred to the network and the physician's problem list by pressing update button 172. Highlighted entries can be removed from the Problem List 166 by pressing delete button 174.

ave button 176 and Exit button 178 perfon-n the usual functions, and preferably provide options to cancel changes, and the like. Data entry box I 80 permits an unlisted condition to be 11cèved in, or otherwise entered character-bv-character and paging buttons 142 move between lists.

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Given the medical, commercial and lec!al sitrnificance of the transactions executed and
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the data generated by use of the system of the invention described herein, as well as the value of that information to the patient, the physician and many other organizations, maintenance of accurate historical records, or archiving, is desirable, or essential, and preferred embodiments of the invention provide archiving at a host computer facility 106.

Data storage burdens attendant upon long-term archiving are substantially relieved by using virtual patient records, as described herein. Pursuant to the principles relating to the use of virtual patient records dynamically created from source data record elements, the invention prefers to archive such data as will enable a full and accurate record of the past to be regenerated from diverse sources, rather than recording the past verbatim. Date and time stamped record elements allow recreation of a virtual patient record at any point in time.

Preferably, the data logged into archives comprise all data relevant to a patient's diagnosis and therapies, data relevant to the user's prescribing activities, including the prescriber's relevant electronic communications ("e-mail") with third parties (pharmacies, laboratories, other health care providers, or potential providers, to the patient, and so on) and access audit data as to parties accessing the patient's or prescriber's personal data.

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eferring to Figure 16, the lefthand side of the diagram shows an arrangement of services and devices that provide a downstream flow of data and communications resources to users of the prescription management, or other svstem described herein.

The righthand side shows sources from which desired data and data elernents may be drawn and pathways for those data to reach the user, the flow being marshalled by a centrally depicted host computer.

hown schematically in Figure 16, are a number of user interface devices 200 and a desktop computer 201 communicating via any of a variety of communication services 202, through a gateway-router 204 with a host computer facility 206. Tile drawing depicts schematically how a group or pool of users working with interface devices 200 or computers 20 1, running the prescription management software of this invention, can be serviced by host computer facility 206. Those skilled in the art will appreciate that the schematic layout shown in Figure 16 is described in terms of its logical architecture and that the actual physical disposition of elements may be quite different.

In addition to coordinating system-related communications, especiallv retrieval of source data from remote databases, gateway-router 204 can manage supplementary services such for example as a paging service 208 or any other relevant desired function.

Interface devices 200 are depicted as small form factor, handheld devices, or PDA's, communicating wirelessly over a WAN, a proprietary wireless service, or a cellular digital packet data service, or the like. Desktop computer 20 1, which may be a
portable, notebook or other higher form factor computer, connected to communications gateway-router 204 via a local area network labeled LAN,. which connection could equally well be via modem, infra-red, wireless or the like, depending upon the circumstances. Any suitable network may be used, depending upon the userls equipment and the location of desired resources. Wired or wireless, local or wide area networks, or mixed networks, are suitable.

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outing to the appropriate service and other communications technicalities
are coordinated by communications gateway.router 204 which is networked
or otherwise connected with host computer facility 206.

15 Other prescribers (or other professionals in different environments)
may use different methods to communicate with host computer facility 206
using a two-way digital data communication svstem across a network.

till other users may be supported by other host computer facilities
communicating in their turn with host computer facility 206 using
appropriate network services and providing communication links or
pathways between such other users and physician users supported by host
computer facility 206. uch organizations employing one or more each of
both users and host computer facilities are intended by references herein
to "network" or the "network".

Communication services 202 can be any service providing effective two-way
data transfer between users 200 and host computer facilitv 206. As
labeled, some possible communication services 202 are wired local area
networks "LAN,...LAN,,", wireless local area networks "WLAN , ... WLAN,,"
and proprietary radio frequency packet data networks, such as A DI and AM
(trademarks of their respective proprietors), cellular digital packet
data networks "CDPD I ... CDPDn" and so on.

Not shown is awire telephone connection between a user device 200 and
communications gateway-router 204. This is of course a possible
embodiment of the invention and it is also, to be understood, local area
networks LAN, could comprise a single desktop computer or a
facifity-based networked system of multiple desktop, or other computers.

Communications gateway-router 204 manages communications through these
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10 various media services and provides consistent interfaces to users at
devices 200 and to host computer facility 206, regardless of which
communication service 202 is used.

As referenced hereinabove, host computer facility 206 can comprise a
client-server system in which a file server or database management
server, or cluster of such servers, manage data storage and traffic
functions, providing high volume data availability to multiple
intelligent clients linked, typically over a local area network, to the
server or servers.

Exchanging data, programs and processing services across this system,
user interface devices 200 and host computer facility 206 support

applications such as the prescription management system of the invention, E-Mail services and any other desired applications, for example patient encounter management programs, diagnostic procedure management programs, and the like, in an analogous manner to conventional client-server supported operation of such applications.

Host computer facility 206 provides intelligent network services to user devices 200 and 201 and may support ancillary services, especially for example, as described hereinbefore, patient-directed data access control software. Prescriber-directed data access control software or organization-directed data access control software could also run in an application separated from the prescription management svstem, but is preferably integrated therewith as a component of a user initialization routine.

Conveniently, patient interface components of the patient-directed data access S control software are run at separate stations from the point-of-care locations used by prescribers and are located, for example, in administrative or reception areas of health care facilities or managed care organizations. Here, data access rights may be read off a patient's data access control card, and such cards may be issued, under control of software supplied by, and in communication with host computer facility 206.

The level of software and data resident on interfaces devices 200 can be varied according to their physical capabilities and user or system administrator preferences.

At a minimum, and for device redundancv, interface devices 200 need have resident neither files nor software, beyond what is supplied with the device off the shelf.
o long as the user interface device has all operating system and is communicationsequipped, they may establish communication with host computer facility 206, using a separately supplied electronic address for that facility and may upload necessary program components and data files, including such personalized user profiles as I-lave been established by the user's prior experience with the system and which have been stored at the host computer facility 206, are called from a remote host computer facility supporting other users.

Neither such program components, nor data, need be stored on the interface device 200 but, where the device 200 has adequate storage capacitv, it will be more convenient and faster-loading for a user to maintain configuration and user profile files, along with limited amounts of relevant drug, and possibly patient data, on the user's local

interface device 200. Preferablv, however basic system access software is required to be installed on the user device before system resources can be accessed.

uch basic system access software can be activatable after reported loss or theft to disable system access capabilities and to render anv stored proprietary data inaccessible to unauthorized users.
Host computer facilijX
Host computer facility 206 provides full software support for user interface devices 200 and maintains complete program files for the prescription management system along with e-mail services and any other non-personal applications that may be needed by users of devices 200 beyond the basic operating systems and utilities, and the like, with which the devices are originally equipped.
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Host computer facility 206 maintains databases of patient infon-nation for patients encountered or whose records have previousl v been viewed by users of devices 200 in response to calls sent via host computer facilitv 206, (and logged by it for audit purposes) but, in keeping with the preferred practice of the present invention, host 1 5 computer facility 206 does not maintain patient records in permanent storage. It could however be used to maintain patient record components that are source components to users of devices 200 for which this particular host facility 206 is, at it were, their "home" facility.

Important functions maintained by the host computer facility 206 are information locator databases and advanced directorv and routing services, including the following.
i) a user device and system registry enabling communications to be routed to the target user;
ii) a patient information directory service enabling access the system to access remote databases to retrieve patient record components for compilation of virtual patient records as described above;
iii) archiving of transaction logs and records, and of audit logs;
iv) patient drug formularies and fon-nulary guidelines or locators to access
same;
v) libraries of alerts and other svstem displaved messages; and
vi) access control software and related data files for patients, care providers and organizations.

Drug and condition lists and some drug information are also maintained on the host computer facility 206, but these are preferably either synchronized or refreshed at intervals (e.g. overnight) from source databases of such drug information. More detailed drug information (e.g. U. . Pharmacopeia information) can be retrieved from remote databases by

host computer facility 206. Host computer facility 206 also maintains directory services for accessing such drug related information, formularies, guidelines alert messages and the like and updates this data remotely from source databases maintained by the proprietors of the information.

Also in addition, host computer facility 206 can off-load data-processing functions from interface devices 200, or conduct such functions in background to provide support for the relatively limited processing capabilities of devices 200.

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A further import-ant function of host computer facility 206 is to retrieve multiple elements of a single patient record from multiple heterogenous remote databases and to deliver them to users for assembly into a virtual patient record by an interface device 200 or 20 1, in response to the user's call for that record.

Host facility 206 can reach out nationally, or internationally, for example across the INTE NET (trademark) to multiple remote databases such as remote databases 2 1 0 shown on the right hand side of Figure 16, to provide to users of interface devices 200 data resources beyond (and potentially more current than) those available from direct storage in the device or at the host facility.

Communications
Communicationbetweenhostcomputerfacility2O6andremotedatabases2lOwill usually be via wire lines such as telephone, or local or wide area network communication via copper line, or optical fiber, or any other suitable communication medium. Clearly, host computer facility 206 can access any remote third party database with which appropriate arrangements have been made, or can be made on line, and some possible source databases for patient records components are labeled as "HMO's, Hospitals Insurance, Drug Benefit Cos, Phan-nacies, Labs and Independent Physicians". Drug information may be additionally sourced from pharmaceutical companies' research centers, reference libraries, or publishers and the like.

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One or more pools of users of devices 200 and computers 201 constitute a valuable professional audience and the system provides a valuable means enabling such third party database proprietors to become data publishers and electronically publish or post their databases or on the network to reach that audience.

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Using recognizable common record element identifiers, for example patient identification numbers or drug identifiers, host computer facility 206 forages across available networks for similarly identified record elements to retrieve. Employing its information directorv services as locators, host computer facility can retrieve a variety of data including patient-specific data, application-specific data (users preferences and the like), organization-specific data (formulary guidelines, for example) and general drug or prescribing data, e.g. from MEDLINE.

To assist with compatibility problems with the legacy systems operating at remote databases 2 1 0 and to avoid heavy volumes -of user calls, via the systems of the present invention, interfering with or slowing down the daily operations at the proprietary facilities supporting the remote data bases 2 1 0, this embodiment of the invention provides, at each of a limited number of remote databases 2 1 0 known to be a significant source of patient record elements, a dedicated data warehouse 212.

Data warehouses 212 can be real or functional, depicting either actual physical embodiments of svstem-dedicated services located at the facilities of remote
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databases 2 1 0, or logical functions executed at the host computer facility 206.
Data warehouses 212, host computer facility 206, communications router-gateway 204 and communications services 204 are components of a conceptual integrating network 214 which brings users of devices 200 and 201 transparent access together with the resources available at remote databases 2 1 0, and preferably gives those users a seamless appearance, as though data stored piecemeal at multiple remote databases 212 were directlv available from a single file across a local area network.

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To facilitate connection with heterogenous databases, and to give their proprietors fluent access across the network, it is preferred that the system provides uniform application programming interfaces, remote API's 216 for use by third party developers. Compatible user API's 218 on the downstream side provide similar standardized connectivity with user devices 200 and 20 1.

Integrating network 214 and API's 216 and 218 permit easy system integration,
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allow third parties to develop end-to-end communications solutions.with standardized third party communication across the network and a data "firewall" for securitV.
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Data Warehouses 212

Each data warehouse 212 maintains replicated copies of relevant data sets obtained by read-only access of remote databases 2 1 0, which data sets are maintained synchronously with updated source data at remote databases 2 1 0, or are periodically refreshed therefrom, preferably at frequent intervals. Data warehouses 212 can also provide search and retrieval facilities and, in particular, provide protocol interchange and reformatting capabilities to reformat or otherwise standardize data and communications across network 214, for any application to use. Preferably, to facilitate compliance Nvith the desired auditability of the transactions and data accesses of preferred embodiments of the invention, data warehouses 212 screen data incoming from associated data warehouses 2 1 0 for date-stamping, and preferably, also time-stamping, of individual received data or record elements, and reject those that lack such stamps. Preferably also, the date stamp indicates origination, creation or updating of the data element, rather than being merely a date of entry of the data element into data warehouse 212.

ource data generated by point-of-care or other transactions at user interface devices 200 or computers 20 1, can be directly posted to remote databases 2 1 0 across I 0 network 214 which bears two-wav traffic. As will be apparent from the disclosure herein, remote databases also include data from other places, for example pharmacies, laboratories and testing facilities.

Communications gateway-router 204 also maintains a physician-device directory 1 5 providing routing or access information needed to establish communication protocols with each individual physician. This device directory service can maintain an electronic address, a device identifier or device configuration, operating system information and user device communications protocols for each user device supported by the gateway-router. User ID's can be listed-separately and in preferred embodiments are accompanied by a prioritized listing of one or more device addresses where. the user may be accessed.

Other temporary or permanent update means are provided to enable a user to access the host computer facility from more than one device, preferably using an address that is device-independent.

It will be understood that an individual host computer facility 206 can serve one
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group of users that may, for example, be defined geographically and may number from, for example, as low as IO or 20 users in the early days of establishment of the facilitv to hundreds and thousands as the facilitv matures. To service more users or to service users in other geographical

areas, additional host computer facilities 206 can be established as centralized or regionally distributed hubs. uch additional host computer facilities 206 will, in all likelihood, access many of the same remote databases210. Preferably,svAtchingorreroutingmeansareprovidedtooptimize data traffic loads between multiple host computer facilities 206.

It will also be understood that a national or international network can be created by establishing a sufficient number of host computer facilities 206 in strategic locations, each serving a local client base of, for example camptis or regional users, with interface devices 200.

Surrima
The foregoing description has emphasized an approach to therapy prescribing which records an association between a therapeutic agent (dnig) and a condition or problem 1 5 targeted for resolution or amelioration by the prescribed therapeutic agent.

ignificant benefits derive from organizing known therapeutic agents according to conditions for which they are known to be effective, and emphasis has been placed herein on a drug selection and specification which begins with selection of a problem or condition to be treated, because this is be an appealing and beneficial approach in many circumstances. Frequently however, the physician may know exactly what drug they wish to prescribe, in which case they can proceed to a direct drug entry screen, and then specify the condition targeted by the prescribed treatment.

While emphasis has also been placed in the principle examples on the prescription of drugs, it%rill be appreciated that the invention can be beneficially applied to the specification of other therapies and technical remedies for example to the specification of surgical procedures, physical therapies and diagnostic testing.

Preferred embodiments of the invention include quick and easy routines for directly posting a drug to a prescription , without prior condition selection, such routines preferably being by-passed. In order to gain the subsequent historical review and outcome study benefits described herein, it is preferred to provide for inclusion of a treatment objective of the prescribed drug in the prescription record before completion of the prescription . The treatment objective can be rapidly selected from a system-supplied list of a patient's existing or historical conditions, or through powerful system-aided selection of a new condition. While a default patient condition or problem may be suggested by the system for a particular prescribed drug, it is preferred that such default be actively confirmed by the prescribing user before being accepted by the system.

To accommodate direct prescribing by drug name, Drug field 88 of the prescription creation screen of Figure 3, can open a personalized or customized user-activatable drug list, or proceed to comprehensive system drug lists to enable rapid specification of familiar or unfamiliar drugs prior to condition selection. Drug dosage selection
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1 5 then proceeds as described above. Before leaving prescribing zone 44 of the prescription creation screen 39 the system can require an appropriate entry to be made in Condition field 86.

Other preferred embodiments enable the patient, the prescribing physician and the relevant organization to control the flow of their own data by predetermining access rights to that data. Every transaction can be stamped with a patient identifier, a prescriber identifier and, if appropriate, an organization identifier, as well as with the date and time of day.
Emphasis on preferred, historical or customized short lists of drugs and conditions enables an attractive working environment to be provided even on relatively low power PDA's. hort list data may be maintained on the user device providing rapid responses in the user's most common prescribing situations. Less common situations entail calls to the host computer facility, in which circumstances delavs of a few seconds while data is retrieved from the network are quite acceptable.

System requirements
User software components of a currently preferred embodiment of prescription management system described herein are designed to run under an operating system that preferably supports a full or modified version of M -DO @ (trademark,
Microsoft Corporation) WINDOW " (Microsoft Corporation) or other systems with user-friendly graphical interfaces, for example Apple Computer Co.'s MACINTO H (trademark) or NEWTON (trademark) operating systems and General Magic's MAGIC CAP operating system. Other graphical environments can be used or are being developed and other embodiments of the invention may be suitably modified to optimize the application to take advantage of the unique characteristics of each such operating system environment.

The programming language used to write system software depends upon the environment of the various system components. In their present stage of development, some handheld PDA's require applications to be written with the tools provided by their respective operating systems such as NEWTON or MAGIC CAP (trademarks). For other devices such as those supporting Microsoft's WINDOW (trademark) operating system, including some PDA's, a range of languages can be used including for example, popular programming languages such as Microsoft

Corporation's"C"orBorlandIntemational's"C++". ForAppleComputer's
MACINTO H (T ADEMA K)-based systems, languages such as THINK
(T ADEMA K) are appropriate.

The system is particularly advantageous when implemented on any of a
variety of portable computer stations especially handheld units such as
personal digital assistants and other personal information communicators
equipped with wireless communicators. A preferred embodiment for mobile
professionals comprises such a handheld unit with two-wav radio or
infrared communication facilities. orne such
devices are referenced in a "BUYE ' GUIDE: PE ONAL DIGITAL A I TANT
PC WEEK August 29, 1994, pages 89 and 94 the disclosure of which is
hereby incorporated herein by reference thereto.

For compatibility with the currently rather limited perfon-nance
specifications of such desirable handheld devices the prescription
management system of the invention is preferably designed to minimize the
storage and processing requirements placed on the user's terminal and to
off-load storage and processing to host computer facilities.

Thus, the system's support architecture aims to supply to the user
terminal only essential data required for screen displays and other user
functions, on an as-needed basis, while the network stores applications
and data files, for example at the host computer facility.

Modified Embodiments of the Invention
While the invention has been described with a reference to a particularly
valuable embodiment of a prescription management systern, it will be
understood by those skilled in the art that alternative embodiments of
tile invention can bring valuable benefits in their respective fields
where informed choice is desirable and can be facilitated bv interactive
computer-assisted decision-making, especially in situations where
decision-relevant data is or can be drawn from multiple heterogenous
remote databases.

ome such possible applications of the invention are to the specification
of laboratory tests and also in the veterinarv field, and to
non-pharmaceutical environments where benefits such as valuable
historical records and follow-up studies, as well as quality control
improvements, can be obtained from coupling diagnostic conclusions with
specified problem solutions.

Thus, according to one such a modified embodiment of the invention,
laboratory test information can be presented to a prescribing
professional by first listing patient conditions which the professional
wishes to explore more fully by specifying one or more specific

laboratory tests, by reporting the laboratory result and suggesting
LUILILr-r testing for differential diagnostics. The system then provides
a selection of laboratory tests known to be useful in evaluating the
relevant condition, that selection and organization of laboratory tests
being made in a manner similar to that described for therapeutic drugs in
the preferred embodiments herein, and moves on to create, select and
order appropriate cost-controllable diagnostic testin i
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comparable manner to that described herein for creating a prescription .

For example, an analogous diagnostic application may provide
cost-effective routes to rule in or rule out specific diagnoses. Die
specificity and sensitivity of individual procedures can be translated
into positive predictive values and negative predictive values. By
applying decision theory and analyzing probable outcomes of procedures or
combinations of procedures in the light of the patient's
bio-characteristics and known conditions, diagnostic protocols can be
worked up and maintained with current recommendations. Evaluation of the
patient's history can enable pretest probabilities to be established and
used to modulate the predictive value of one or more tests. Thus the
patient's history can drive the selection and establishment of an optimal
diagnostic test matrix for identifying a patient's condition or
conditions with good specificity and confidence levels.

Test requirements relating to patient preparations, fasting for example,
and sample collection can be system specified. By generating
system-maintained identifiers (e.g.

bar code labels) for attachment to samples at the point-of-care, a chain
of evidence for rigorous sample accessioning can be begun.

Thus, a range of possible conditions can be evaluated in a differential
diagnosis format designed to rule in or rule out a target condition, or
conditions, depending upon the results of specified tests.
Extensions into the veterinary field will be apparent to those skilled in
the art in that
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instead of the physician user feferenced herein, reference to a
veterinarian is
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appropriate, and the patient %vill be an animal such as a pet dog or cat
or valuable livestock, such as a steer or breeding pig or a race horse or
breeding stallion.

Again, although the invention has been described in its preferred
embodiments with reference to a physician user it will be apparent that

other medical professionals, especially those having prescribing authority, can benefit from applications of it.

In a more general sense, the invention provides a service professional with significant new benefits, especially during a service encounter with a customer or client, in I 0 selecting, specifying or providing technical remedies to consumer problems. For example, in specifying automotive replacement parts a service technician can benefit from an automotive service management system according to the invention in which a database of replacement parts is classified according to the service problem for which the parts might provide a remedy. Thus, for a customer with the problem of 1 5 break squeal, the system may provide a list of parts, for example, brake pads, brake pins, brake shims or brake rotors, any of which may provide a remedy to the customers problem of brake squeal. Existing systems permit a service technician, having once identified the type of part they need, to obtain a number or part price and inventorv on that part for the customer's specific model of car.

However, known systems do not permit the professional to query the system by customer problems, nor do they provide a summary of all facets of a solution to a problem leading to a summarized cost of treatment. In addition the inventive system can provide access to technical literature on relevant problems, for example an explanation of the factors causing bra1ce squeal which can be printed out for customers. 'niis is a rather simple example. More complex examples will be apparent to those skilled in the automotive and other arts, especially as this art develops, with sophisticated engine management and other microprocessor controlled systems raising new problems and new technical solutions being required. The inventive system can provide customer problem lists useful for outcome analysis to drive the development of better cars.

Of great value in the automotive and allied fields, equating a parts supplier, such as a factory or warehouse distributor with a plan benefit company is the ability to provide new product descriptive and price information or updates from multiple sources dynamically, in real time as transactions are created. Noting the desire of a benefits company to apply practical selection guidelines in an unobtrusive manner to the prescribing process, an equivalent technique can be used by car factories to help control warrantv service decisions at their dealerships.

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In another embodiment of the invention illustrating its generality, possible insurance vendors and coverage infon-nation may be classified according to custorner problems so that, for example, an insurance agent mav list different vendors and covera e
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providing specific technical remedies to a customers specific; problem, for example, a 1 5 recent major automobile collision claim. The relevant novel supportive database could include information differentiating between parties at fault, collision damage, personal injury settlements and so on. In both these examples a problem history related either to the customer or to the customer's automobile can also be created.

It will be clear to those skilled in the art that use of the prescription management system described herein, employing carefully maintained databases of accurate, reliable prescribing data will produce high quality prescriptions free of many of the problems now plaguing prescription drug use. With confidence that a physician is prescribing appropriate, cost-effective drugs selected from user-personalized lists which link to comprehensive condition and drug lists including the latest available drugs, and that the prescribed drug has been reviewed for contraindications, patients benefit, oversight of the prescribing process by benefit companies and regulatory bodies can be reduced, and litigation resulting from prescribing errors will be reduced.

ignificant improvements in the quality of care, substantial savings and the 30 elimination of waste can accrue to a national or regional health care svstem from widespread deployment of the inventive prescription management systern described herein.

Physical embodiment of system software
The foregoing specification, readwith the accompanying drawings provides an extensive disclosure of, inter alia, various embodiments of systems and software facilitating professionals to select or specify technical products to solve practical problems, and also to create, or assist the professional to create, new products which will assist the professional or their client in achieving desired problern-solving goals.

It will be understood that the svstems and software referenced herein include, either explicitly, or implicitly, software implemented on computers or other appropriate hardware, including user devices such as the personal digital assistants described herein, and such other intelligent data processing devices having a processor, data storage means and the abilitV to support an operating system, with or without user interfaces (for example, file servers,), as mav be useful in achieving the objectives of this invention.

oftware components and applications embodying the invention can be distributed in electronic bit stora e on magnetic, optical, bubble or other media, optionally in
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transportable form to be interactivewith an electronic reading device,

for example on computer or optical diskettes, or may be distributed over wired or wireless networks for storage by the recipient on such media.

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Preferred embodiments of the invention provide such media-stored software in a commercial package accompanied by instructions in printed book or booklet form, for deployment of the software on particular embodiments of general purpose computer to cause same to operate as a special purpose computer, in accordance with the objectives of the invention. License agreements, and registration means for updating may also be included. Alternatively, the instructions may also be provided as data files.

It will further be appreciated that such media-stored software constitutes an electronic customizing machine which can interact with a magnetically or optically cooperative computer-based input device enabling the computer to be customized as a special purpose computer, according to the contents of the software. To cause a computer to operate in such customized, special-purpose mode, the software of the invention can be installed bv a user, or other, and will usuallv interact efficiently with the device on which it is resident to provide the desire special-purpose qualities, only after selection of configuration parameters. When so configured, the special-purpose computer device has enhanced value, especially to the professional users for whom it is intended.

While some illustrative embodiments of the invention have been described above, it is, of course, understood that various modifications will be apparent to those of ordinary skill in the art. uch modifications arewithin the spirit and scope of the invention, which is limited and defined only by the appended claims.

Thus, while certain aspects of the invention- have been disclosed as embodied in connection with a prescription management system, it will be apparent that they have broader application in other systems or environments. ome of these aspects are: dynamic assembly of records from source record elements retrieved across a network from heterogenous remote databases; requirements for those elements to be time- and date-stamped for retrospective recreation of records from archival logs; physician-centric drug formularies; data-access control systems and software; the novel directory services described herein and associated online point-to-point e-mail and data retrieval systems; data retrieval networks with API-enabled end-to-end transparency; novel outcome studies, monitoring and alerting procedures, studies and related products; novel scheduled dosage drug packs and dispensing devices, and so on.

Claim

Claim 1. A computer-implemented prescription management system for use
by a prescriber in creating a prescription at a point of patient care,
the prescription being usable by a pharmacist to dispense drugs, the
prescription management system
comprising:
a) electronic posting means to select and capture in the prescription :
I) a patient identifier;
ii) a prescribed drug (I 18); and
iii) a dosage for the prescribed drug (I 1 8);
1 0 and
b) a displayable library of prescribable drugs (I 18);
characterized in that the electronic posting means enables selection and
capture of iv) a patient condition (I 16) intended by the prescriber to
be treated by the prescribed drug (I I 8). Claim 2. A prescription
management system according to Claim I characterized by having means to
track preferred data usage by a user and to adapt data displays to favor
such preferred usage, whereby the system learns and adapts to a user's
habits. Claim 3. A prescription management system according to Claim 2
characterized in that at least one- said preferred usage data display
comprises a personal-preference condition-selection list for each system
user.
Claim 4. A prescription management system according to Claim 2 or 3
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characterized in that at least one said preferred usage data display
comprises a personal-preference drug-selection list for each system user.
Claim 5. A prescription management system according to Claim I further
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characterized by comprising a patient history record displayed online,
the patient history record listing electronically available prior
prescriptions, the prior prescriptions each including a prescribed drug
(I I 8) and a condition treatment objective for each drug prescribed,
system-created prescriptions being system-added to the history record. 5
Claim 6. A prescription management system according to Claim 5
characterized by comprising a patient condition list for selection of a
patient condition (I 16) for posting to the prescription , the patient
condition list includes patient conditions (I 16) listed in the patient
history record. I 0 Claim 7. A prescription management system according
to Claim I characterized by comprising a source-oriented data-retrieval
subsystem, the data retrieval subsystem accessing at least one
data-retrieval network to supply an array of up-to-date prescribing
infon-nation and patient-related data to tile point-of-care from remote
source databases.
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Claim 8. A prescription management system according to Claim 7
characterized in that the data-retrieval subsystem is linked to the
prescription management system to provide one or more indicators of

allergy and interaction alerts, drug formulary changes and new drug approvals, and to lock out or warn against, the prescribing of inappropriate or recalled drugs. Claim 9. A prescription management system according to Claim 5 characterized by comprising a patient history record dvnamicallv assembled online in response to a user request from multiple source record elements retrieved from multiple heterogenous remote databases. Claim 10. A prescription management system according to Claim 9 implemented on a user interface device configured for networked digital communication with a host computer facilitv, characterized in that tile patient history record is retrieved in the form of record elements from the remote databases bv the host computer facility in response to a call from the user device, the remote source databases being selected and identified according to the patient's prior geographical locations and health-care service providers. Claim I 1. A prescription management system according to Claim 5 characterized in that the patient history record is a virtual patient record newly assembled online in response to each user request for the record thereby to be current with regard to
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possible remote updates of the source record elements. I 0 Claim 12. A prescription management system according to Claim I I characterized in that the host computer facility logs the tirne, date and user calling for the virtual patient record to provide ail audit trail of access to the patient's record, or a provider's or organization's data. 5 Claim 13. A prescription management systern according to Claim I I deployed comprehensively throughout a geographical area, demographic, company, plan or community group whereby all drug prescriptions created in the area are products of the svstem and characterized in that all the drug prescriptions are posted to source databases accessible to the svstem whereby a complete patient history record of all drug prescriptions created for the patient in the geographical area, demographic, company, plan or community group can be listed in the dynamically assembled virtual patient record. Claim 14. A prescription management systern according to Claim I characterized in that the drugs (1 18) in the drug list are classified according to a patient condition (I 16) for which the drugs (I -1 8) have efficacy and the prescription management system further comprises a patient-condition specification procedure for selecting the condition (I 16) from groups of possible conditions (I 16) and an onscreen drug selection procedure for selecting the prescribed drug (I 18) from the library, listing multiple drugs (I 18) for treating each the patient problem. Claim 15. A prescription management svstem according to Claim I characterized
by comprising:
c) displayable patient drug fonnulary information to indicate to the prescriberuser selected ones of the prescribable drugs included within a drug formulary

associated with the patient to enable compliance with drug formulary guidelines at the point-of-care. Claim 16. A prescription management system according to Claim 15 characterized in that the patient drug formulary display means comprises a condition-driven forinularvdruglist(120),andacondition-drivennonfonniiiarvdniglist,thedrug I lists being changeable according to the patient selected.

Claim 17. A prescription management system according to Claim 15 or 16 characterized in that the svstem provides dnig efficacy guidelines based on patient information and fori-nularv information.

Claim 18. A prescription management system according to claim 3 characterized in that the prescriber-user's personal-preference list of drugs is displayed with fori-nulary drugs indicated.

Claim 19. A prescription management system according to Claim 15 or 16
characterized by including relative cost information for displayed formulary drugs.

Claim 20. A prescription management system according to Claim 15 or 16 characterized in that tile drug forinulary is generated by a prescription benefits management company by providing computer access to remote databases containing the drug formulary information whereby appropriate formulary drugs are presented to the user on screen on a user interface device deployable at the point-of-care, to facilitate compliance with dnig formulary guidelines at the point-of-care.

Claim 2 1. A prescription management svstem according to Claim 15 or 16 characterized in that prescribability of a drug pursuant to formulary guidelines is formulary-qualified according to the patient condition (I 16).

Claim 22. A prescription management system according to Claim 15 or 16 characterized by comprising built-in logic for accessing drug formulary information from multiple drug formulary providers wherein the drug formulary list is selected from the multiple available drug formularies according to the patient identification, the patient having a prior arrangement with the drug formulary provider to provide I 0 prescription -related benefits to that patient, the drug formulary list information being dvnamically presented to the prescriber-user in the forrn of at least one selection of patient-specific formularies from which a fonnulary status indication relevant to a patient therapy-related choice made by the prescriber-user is made. Claim 23. A prescription management system according to Claim 22 characterized by comprising network data communication means to update and maintain the multiple available formularies from remote source databases of formulary infon-nation. Claim 24. A prescription management system according to Claim I characterized by comprising means to categorize and display the patient conditions(I 16) in multiple condition lists (I 12), the condition lists being selected from the group consisting of a personal condition list of conditions encountered by the prescriber, a historical

condition list of conditions exhibited by the patient, one or more prescriber-customized condition lists, a body system condition list, conditions organized according to disease pathology, therapy, personal knowledge and others. Claim 25. A prescription management system according to Claim 24 characterized in that drug selection is condition driven and the prescriber selects a patient condition (I 16) to be treated via at least one of the condition lists.

Claim 26. A prescription management system according to Claim 24 or 25 characterized by intelligent data access means for a prescriber-user to access a large body of drug data selections via multiple condition-driven routes to provide multiple mapping so that the user can find a suitable drug or selection of drugs via different pathways according to their preferred work methods. Claim 27. A prescription management system according to Claim 1, 5, 15 or 24 characterized in that the electronic posting means can select and capture dosage and route of administration infon-nation, and optionally, length-of-treatment and generic substitution authorization inforrnation, for a selected drug, the information - being system-available for all listed drugs. Claim 28. A prescription management system according to Claim 27 characterized by comprising network data communication means to update and maintain the dosage information the dosage inforrnation being dynamically supplied from a remote source database when called bv the svstem. Claim 29. A prescription management system according to Claim 1, 5, 15 or 24 characterized by comprising a prescription expiration routine including dosing, amount and expiration drug quantifiers and system calculation of a relationship between the drug quantifiers where the system provides default values for unspecified ones of the drug quantifiers in response to user selection of one or more of the drug quantifiers and optionally patient history information, formulary information indicating preferred drug lists for treatment. Claim 30. A prescription management system according to Claim 1, 5, 15 or 24 characterized by comprising a patient data access control subsystem including data access control specification means enabling a patient to authorize a user to access the patient's history data and by comprising data access control means whereby only an authorized user can access the patient's data. Claim 3 1. A prescription management system according to Claim 1, 5, 15 or 24 characterized by comprising a patient data access auditor, the patient data access auditor generating an access record logging information as to the time date and identitv of entities accessing the patient history data, the prescriber's prescribing history or the organization's prescribing history, to provide a patient data access audit trail, a prescriber's data access audit trail or an organization's data access audit trail. I 0 Claim 32. A prescription management system according to Claim 1, 5, 15 or 24 characterized by comprising a patient data access subsystem providing patientdirected control of the flow of their own data. Claim 33. A prescription management system according to Claim 32 characterized 1 5

in that the patient-directed data-access control is achieved by centrally inputting to the patient data access subsystem at a host computer facility, patient-generated record-access specifications deten-nining which parties can access what data during what period of time. Claim 34. A prescription management system according to Claim 32 characterized in that the patient-generated record-access specifications provide a patient security profile in a pre-authorization file the pre-authorization file being used to control access to the patient's data. Claim 35. A prescription management system according to Claim 1, 5, 15 or 24 characterized by comprising user-related historical records generated by operation of the system by a prescriber-user, a user data-access control subsystem including dataaccess control specification means enabling a user to authorize selective third party access to the user's historv data and comprising data access control means whereby only an authorized third party can access the user's data which control means determines what data type may be accessed by what organization or provider. Claim 36. A prescription management system according to Claim 36 characterized by comprising a user data access auditor, the user data access auditor generating an access record logging information as to the time date and identity of third parties accessing the user history data, to provide a user data access audit trail. Claim 37. A prescription management system according to Claim 1, 5, 15 or 24 characterized by comprising organization-generated source data retrievable for I 0 display in the prescription -management system from at least one remote database, an organization-directed data-access control subsystem including data-access control specification means enabling an organization to authorize selective third party access to the organization-generated source data and comprising data access control means whereby only an authorized third party can access the organization-generated source 1 5 data. Claim 38. A prescription management system according to Claim 37 characterized by . comprising an organization data access auditor, the organization data access auditor generating an access record logging information as to the time date and identity of third parties accessing the organization-generated source data to provide an organization data access audit trail. Claim 39. A prescription management system according to Claim I characterized by comprising newly created prescription evaluation means to evaluate a newly 2 5 prescribed drug for system-known patient allergies or drug-to-drug interactions, or drug-to-multiple drug interactions and absolute contraindications with currently prescribed drugs, as known to the system. Claim 40. A prescription management svstem according to Claim 1, 5, 15, 24 or 39 characterized by comprising a drug alert subsystem for communicating alerts relating to unfavorable or cautionary characteristics of particular drugs wherein the alerts are associated with system information on the drug so that when a user calls up
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the drug in question, they receive the warning or alert, or other special message. Claim 41. A prescription management system according to Claim 39 characterized in that the drug alert subsystem is operative to communicate drug withdrawal information to system users electronically in real time or when the withdrawn drug is selected for prescribing or a warning is posted directly to the prescription . I 0 Claim 42. A prescription management system according to Claim 41 comprising prescription completion control means to prevent completion of a prescription for the withdrawn drug whereby a dnig can be withdrawn from a market in which the prescription management system is deployed in a single day. Claim 43. A prescription management system according to Claim 41 characterized in that current users of a drug or medication can be identified from prescription historv records, referencing not onlv drugs prescribed, but also prescription expiry dates and both the patient and their doctor are electronically notified of the drug withdrawal. Claim 44. A prescription management system according to Claim I characterized by comprising onscreen electronic mail access to other users of the system, the electronic mail capability additionally being linked with the prescription creation function and enabling a prescriber-user to append an electronic record to a prescription or prescription -related record. Claim 45. A prescription management system according to Claim 44 characterized in that the electronic mail provides a platform for accessing other artificial intelligence and expert systems and optionally providing linkage for transaction services such as the ordering and reviewing of scheduling and similar administrative functions. Claim 46. A prescription management system according to Claim 1, 5, 15, 24, 39 and 44 characterized by comprising a patient-selection subsystem whereby preliminary selection of groups of patients can be made by providing multiple patient lists selected from the group consisting of "Today's Patients", "In-Patients". "OutPatients", "Private Patients" and others. Claim 47. A prescription management system according to Claim 46 characterized in that the patient lists are system-maintained, on an ongoing basis, using the latest data available to the svstem and include intelligent patient selection means enabling the user to select a convenient group of patients that has a high probability of including the next patient or patients to be encountered, thereby speeding access and retrieval of a desired patient record. Claim 48. A prescription management system according to Claim 1, 5, 15, 24, 39 or 44 characterized by comprising onscreen access to drug detail information as to indications, interactions, side effects and precautions. 20 Claim 49. A prescription management system according to Claim 1, 5, 15, 24, 39 or 44 characterized by comprising a drug literature-retrieval subsystem to retrieve drug -related information across a network frorn a remote heterogenous database for display to the user in real time. Claim 50. A prescription management system according to Claim 49 characterized in

that the drug literature-retrieval subsystem provides the user with an access point to full disclosure and prescribing information on a selected drug and characterized in that the available drug information is selected from the group consisting of drugtreatment guidelines, one or more literature references supporting the guidelines, details of the particular conditions (I 16) for which a smem-suggested alternative drug has been found effective, adverse conditions, preferred dosages and administration routes, literature sources and other relevant drug-prescribing information. Claim 5 1. A prescription management system according to Claim 50 characterized in that the drug literature-retrieval subsystem is operative to enable a physician, to have a hard or printed copy, or other media form of relevant studies or literature sent to them by onscreen selection, the onscreen selection being system-communicated to a source for the study or literature information.

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Claim 52. A prescription management system according to Claim 50 characterized in that the drug literature-retrieval subsystem is operative to provide a simple nonintrusive technique for brin ng new drug infori-nation to physicians at a point of

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care when creating a prescription .

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Claim 53. A prescription management system according to Claim 32 characterized by comprising an outcome study subsystem for selecting outcome study participants by centrally maintaining patient-directed patient-record-access specifications whereby the system can include records of patients agreeable to becoming study participants in such outcome studies pursuant to indications in their patient-record-access specifications optionally with output of the study data being controlled to comply with access specifications of prescribers and organizations having proprietary rights thereto. Claim 54. A prescription management system according to Claim 1, 57 15, 247 39 or 44 characterized by comprising a new dnig surveillance subsystem to conduct post introduction market surveillance of new drugs for adverse outcomes to the treatment of a specified condition (I 16) or conditions with the newly introduced drug, Claim 55. A prescription management systeni according to Claim 54 characterized in that the new drug surveillance subsystem is operative to monitor patients reporting new problems after having been prescribed the new drug in question, refer such new problems to the physician user to qualify them for medical relevance and then statistically compare a collection of similar reports with data on a pool of similarly treated patients for significance. Claim 56. A prescription management system according to Claim 1, 5, 15, 24, 39 or 44 characterized in that the condition list comprises at least five condition (I 16)s, and the drug list comprises at least five drugs.

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Claim 57. A prescription management system according to Claim 1, 5, 15, 24, 39 or 44 characterized in that the drug information comprises associated condition infon-nation and dosage information for at least about fifty percent of all prescribable govemment-approved drugs. Claim 58. A prescription management system according to Claim 1, 5, 15, 24, 39 or 44 characterized by comprising means to output a newly created electronic prescription in print or other readable media, to local or remote File storage or to remote file transfer as an electronic prescription . Claim 5 9. A prescription management system according to Claim 1, 5, i 5 7 24, 3 9 or 44 characterized by comprising means for transmitting the electronic prescription across a network for fulfillment by a specified pharmacy. Claim 60. A prescription management system according to Claim 57 characterized by comprising a printed dosage schedule output for the patient. Claim 6 1. A prescription management system according to Claim 1, 5, 15, 24, 3 9 or 44 characterized in that multiple physicians accessed by a patient utilize the 30 prescription management sVstem described herein, with common online access to, and assembly of, a patient's prescription history record whereby the prescription history record provides a current record of all new prescriptions for the patient, and the system enables control of prescription abuse by the patient wherein the patient presents a problem or condition to more than one physician to obtain multiple prescriptions with a view to indulging in abusive ingestion or illicit resale. Claim 62. A prescription management system according to Claim 1, 5, 15, 24, 39 or 44 characterized in that the system also provides a patient-related notification from a pharmacy, or from a drug benefit plan linked to the pharmacy, of fulfillment of a prescription , and that fulfillment notification is available to the prescriber, whereby the system enables prevention of prescription abuse wherein the patient pleads loss of a prescription to obtain a duplicate. Claim 63. A prescription management system according to Claim 1, 5, 15, 24, 39 or 44 characterized in that the system also provides a patient-related notification from a pharmacy, or from a drug benefit plan linked to the pharmacy, of fulfillment of a prescription , and that fulfillment notification is available to the prescriber whereby a patient's failure to have a prescription fulfilled indicating discontinuance of the prescribed therapy can be monitored for correction. Claim 64. A prescription characterized by being produced by the system of claim

1 5, 15, 24, 39 or 44 output in a form selected from the group consisting of electronic, paper, digitized voice and fax.
Claim 65. In combination, a host computer facility and a prescription management system according to claim 1, S, 15, 24, 39 or 44 implemented on the host computer facility the host computer facility supporting

network delivery of userrelevant components of the prescription management system to multiple remote user interface devices and providing data and communications resources for users to draw upon employing the interface devices. Claim 66. A combination according to claim 65 characterized in that the host computer facility can communicate with multiple heterogenous remote databases to

retrieve complementary data elements from the databases and comprises:

i) a dynamic record assembly procedure for online assembly of a data record

from the complementary data elements; and

H) a user-device communication procedure to deliver the dynamically assembled record to a calling user-interface device as an integral data component of the prescription management system. Claim 67. A prescription management system for electronic prescription creation by a prescriber at a point of patient care, the prescription being usable by a

pharmacist to dispense drugs, the prescription management system being characterized by comprising electronic posting means to select and capture in the

prescription :

i) a patient identifier;

ii) a prescribed drug; and

iii) a dosage for the prescribed drug;

and an onscreen drug selection procedure having at least one drug list specifying multiple possible prescribable drugs and having drug specification means to select and post a desired drug to the prescription wherein the system calls for, and requires, the prescriber to -enter a condition (I 16) before proceeding to quantification of the prescription . Claim 68. A prescription management system according to Claim 66 characterized by comprising drug formulary infon-nation being a selected list of drugs being preferred for prescribing by a drug benefit provider to the patient. Claim 69. A computer-implemented prescription management system for use by a prescriber in creating a prescription at a point of patient care, the prescription being usable by a pharmacist to dispense drugs, the prescription management system comprising:

a) electronic posting means to select and capture in the prescription :

i) a patient identifier;

ii) a prescribed drug;

iii) a dosage for the prescribed drug;

and characterized by comprising

b) a prescription division subsystem to create a bridge prescription divided into a

local prescription component intended for fulfillment at a pharmacy convenient to the patient and a remote prescription component intended for fulfillment at a remote, lower cost, mail order pharmacy. Claim 70. A

prescription management system according to Claim 69 characterized in that the local prescription component specifies an adequate prescribed drug quantity for short term needs and the remote prescription component provides a 5 longer tenn supply.

Claim 71. A prescription management system according to Claim 69 or 70 characterized in that the electronic posting further selects and captures in the

prescription :

iv) a patient condition (I 16) intended by the prescriber to be treated by

the prescribed drug;

and the prescription management system further comprises:

b) a displayable library of prescribable drugs; and

c) displayable patient drug formulary information to indicate to the prescriber-user selected ones of the prescribable drugs included within a drug formulary associated with the patient to enable compliance with drug formulary guidelines at the point-ofcare. Claim 72. A time- and date-scheduled multi-drug dosage package generated by an electronic prescription according to claim 64, for containing a multi-drug prescription or prescriptions to be taken contemporaneously by a patient characterized by comprising a package having multiple labeled or coded compartments for each of a number of dosing intervals for multiple drugs. Claim 73. A multi-drug package according to claim 72 bearing time-interval descriptors prescription -relevant date, patient and doctor identification and at least one series of multi-compartment drug bays to accommodate a prescribed dosage of a solid drug formulations, each bay being labeled with a time of day at which the dosage in each bay is to taken, zone marlcings extending across multiple I 0 compartments in a series of bays and labeling same as dedicated to an individual drug. Claim 74. A multi-drug package according to claim 73 characterized by being configured as a card, strip, roll, book, a metal foil sheets having tear or press-out 1 5 compartments or by having an accordion-pleat configuration. Claim 75. A multi-drug package according to claim 74 characterized by at least some of said drue dosages being organized into unequal quantities in differently

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timed compartments to facilitate time-related dosage variations. Claim 76. A dosing indicator device usable with an electronically or electro-optically

readable scheduled dosage, compartmented drug package characterized by comprising a time-and-date clock and being adapted to receive at least one scheduled dosage drug package and to inspect that package to determine the presence of a drug dosage in a compartment labeled with a date and time prior to the date and time docked by the device, and an

audible or visual or remote alert triggerable in response to detection of the presence of such dosage. Claim 77. A dosing indicator device according to claim 76 characterized by having light-beam means to target individual package compartments with a light beam to be reflected or diffused by an individual drug dosage or associated light-modulating tag, or by a bar code stamp or label which is required to be removed with each dosage of any drug, the device including a movable scanner that advances in relation to a

package from one compartment bay to an adjacent one, scanning relevant 5 compartments in the bay, as time passes, or comprises an array of photoelectric sensors registering with individual compartments of the package, which are electronically controlled and read in turn, as time passes. Claim 78. A dosing indicator device according to claim 76 characterized by I 0 accommodating, within an aesthetically pleasing housing, a multi-bav scheduled dosage package, a time-and-date clock, a time-related sensor to detect the presence of a drug dosage in the bays one or more alerting systems, associated electronics including a microprocessor, and power supply ineans. 5 Claim 79. A dosing indicator device according to claim 78 characterized by being embodied as a motor-driven single- or multi-drug dosage dispenser to house a tape, or strip-like dosage package, having a time line along the strip and advances individual bays containing one or more dosages for a given dosage time, and presents a single bay for external delivery and removal and administration in timed relationship to the dosage time and triggers one or more alerts if the dosage is not timely removed from the bay. Claim 80. A professional product specification system for electronically creating a technical specification usable by a professional to specify technical products the

product specification system comprising:
a) electronic posting means to select and capture in the prescription :
i) a customer identifier;
ii) a specified product; and
iii) product specifications;
and being characterized by comprising
b) an onscreen product selection procedure having a product benefit list specifying multiple possible customer benefits having a product list specifying multiple possible specifiable products and having product specification means
to select and post a desired product to the specification;
wherein products in the product list are classified according to a customer-useful technical purpose attainablewith the products and the onscreen product selection procedure lists multiple products for providing each tile customer benefit. Claim 8 1. A system according to claim 80 characterized by enabling laboratory test information to be presented to a prescribing professional by first listing patient conditions which the professional wishes to explore more fully by

specifying one or more specific laboratory tests, by reporting tile laboratory result and suggesting further testing for differential diagnostics; by then providing a selection of laboratory 1 5 tests imown to be useful in evaluating the relevant condition (I 16) and to select and order appropriate cost-controllable diagnostic testing.

Claim 82. A system according to claim SI characterized by comprising a diagnostic application providing cost-effective routes to rule in or rule out specific diagnoses, employing the specificity and sensitivity of individual procedures to translate test results into positive predictive values and negative predictive values. Claim 2. A prescription management system according to Claim I characterized by having means to track preferred data usage by a user and to adapt data displays to favor such Prefemd usage, wherebv the svstem learns and adapts to a user's habits. Claim 3. A prescription management systern according to Claim 2 characterized in that at least one said preferred usage data display comprises a personal-preference condition-selection list for each svstem user.

Claim 4. A prescription management systern according to Claim 2 or 3 characterized in that at least one said preferred usage data display comprises a personal-preference drug-selection list for each system user.

Claim 5, A prescription management system according to Claim I further characterized by comprising a patient history record displayed online. the patient historv record listing electronically available prior prescriptions. the prior

AMENDED SHEET (ARTICLE 19)

or prescriptions to be taken contemporaneously by a patient characterized by comprising a package having multiple labeled compartments for each of a number of dosing intervals for multiple drugs, each paclcage compartment being intended for and labeled for a single dosage. Claim 73. A multi-drug pad.-cage according to claim 72 bearing time-interval descriptors prescription -relevant date, patient and doctor identification and at least one series of multi-compartment drug bays to accommodate a prescribed dosage of a solid drug formulation, each bay being labeled vAth a time of day at which the dosage IO in each bav is to be taken, zone markings extending across multiple compartments in a series of bavs and labeling same as dedicated to an individual drug.

Claim 74. A multi-dnig pacicage according to claim 73 characterized by being configured as a card, strip, roll, book, a metal foil sheets having tear or press-out 1 5 compartments or by having an accordion-pleat configuration. Claim 75. A multi-drug package according to claim 74 characterized by at least some of said drug dosages being organized into unequal quantities in differently timed compartments to facilitate time-related dosage variations. Claim 76. A dosing indicator device usable vAth an electronically or electro-optically readable scheduled dosage, compartmented drug package characterized by comprising a time-and-date clock and being adapted to receive at least

one scheduled dosage drug package and to inspect that padcage to deten-nine the presence of a drug dosage in a compartment labeled,"ith a date and time prior to the date and time docked by the device, and an audible or visual or remote alert triggerable in response to detection of the presence of such dosage. Claim 77. A dosing indicator device according to claim 76 characterized by having 30 light-beam means to target individual package compartments vAth a light beam to be
AMENDED SHEET (ARTICLE 19)
Claim 78. A dosing indicator device according to claim 76 characterized by accommodating, within an aesthetically pleasing housing, a multi-bav scheduled dosage package, a time-and-date clock, a time-related sensor to detect the presence of a drug dosage in the bays one or more alerting systems, associated electronics including a microprocessor, and power supply means. Claim 79. A dosing indicator device according to claim 78 characterized by being embodied as a motor-driven single- or multi-drug dosage dispenser to house a tape, or strip-like dosage package, having a time line along the strip and advances individual bays containing one or more dosages for a given dosage time, and presents a single bay for external delivery and removal and administration in timed relationship to tile dosage time and triggers one or more alerts if the dosage is not timely removed from the bay. Claim 80. A professional product specification system for electronically creating a technical specification usable by a professional to specify technical products the product specification system comprising:
a) electronic posting means to select and capture in the prescription :
i) a customer identifier;
ii) a specified product; and
iii) product specifications;
and being characterized by comprising
AMENDED SHEET (ARTICLE 19)
Claim 8 1. A svstem according to claim 80 characterized by enabling laboratory I 0 test infori-nation to be presented to a prescribing professional by first listing patient conditions which the professional wishes to explore more fully by specifying one or more specific laboratory tests, by reporting the laboratory result and suggesting further testing for differential diagnostics; by then providing a selection of laboratory tests known to be useful in evaluating the relevant condition (I 16) and to select and 5 order appropriate cost-controllable diagnostic testing.
Claim 82. A system according to claim 81 characterized by comprising a diagnostic application providing cost-effective routes to rule in or rule out specific diagnoses, employing the specificity and sensitivity of individual procedures to translate test results into positive predictive values and negative predictive values.
Claim 83. A computer-implemented method for dynamically assembling chronologically current virtual client records from multiple remote

databases of

primary source infori-nation characterized by comprising:

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a) online interrogation of possible primary sources of electronically
recorded client history elements to locate record elements for each
specified client; b) maintaining a directory service providing routing
information to the located

record elements;

c) retrieving the located record elements for each specified client from
the respective primary sources using routing information provided by the
directory

AMENDED SHEET (ARTICLE 19)

service; and

d) assembling the retrieved record elements into a complete record for
each specified client. Claim 84. A method according to claim 83 of
assembling medical patient records characterized in that for each
patient, the patient data directory service lists institutional sources
known to have source historical record elements for the patient, against
a unique patient identifier, and record element retrieval is controlled
by patient-specified access protocols detailing permissible access
parameters.

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Claim 85. A computer-implemented medical treatment management method
facilitating a medical professional to order a patient-specific treatment
at a point-of

care characterized by comprising:

a) retrieving multiple data elements from multiple remote heterogenous
1 5 databases which data elements include patient-related data and
historical

treatment data;

b) computer generation of a patient-specific treatment recommendation
from the

retrieved data elements; and

c) computer-transmitted issuance by the medical professional of a
treatment

order after taking the computer-generated treatment recommendation into
account.

AMENDED SHEET (ARTICLE ig)

STATEMENT UNDER ARTICLE 19

Claim I amendments include re-positioning of the characterizing clause in
view of the references cited, minor corrections and the addition of the
last two lines of the claim. Claim 72 has been amended to specify that
each package compartment is intended for and labeled for a single dosage.
'minor corrections have been made to claims 73 and 74. The inventive
system for the first time brings together, in an electronically generated
prescription , both the treatment to be applied and the objective of the

treatment. The system is also convenient, physician friendly by virtue of its presentation of drug lists which facilitate critical data entry, and treatment selection, encouraging physicians to use the system. These are the prerequisites to the claimed system's ability to create a valuable historical data resource which can generate a variety of treatment recommendations to assist a prescribing physician make decisions. Such recommendations can range from patient-specific repeat or alternative treatments to general advisories derived from epidemiological outcome studies. None of the references suggests an electronic prescription system for capturing patient conditions and treatment data which is capable of creating historical records in which the target condition is recorded in association with the prescribed treatment. Brimm et al. Brimm's objective is to automate hospital record-keeping and maintain various task lists (see column 4, lines 10-20). This is quite different from assisting a prescribing physician to make decisions. Brimm discloses a hospital information LAN which lacks any centralized data storage system. Brimm merely shows an order-entry system for maintaining hospital-based data for nurses, not an electronic prescription system. The figures show nurses screens, not screens intended for physician use, for example Figure 5 is a medication flow sheet which records, inter alia, orders previously given by a physician into a task list assembled for a nurse to sign off on. Brimm does not bring a treatment and a patient condition to be treated together in an electronic prescription . Brimm is not intended for physicians and does not provide any means to assist a physician's decision making. Brimm, does not provide a system capable of generating a historical data resource from which treatment recommendations can be made to assist a prescriber. Garcia. Garcia is another hospital computer system recording detailed patient-related information with the objective of prioritizing patient scheduling (claim I last 7 lines). Any treatment or condition data that happens to be captured is not used to drive treatment selection by the physician. Kaufman. Kaufman discloses a drug delivery device which is also nursing focused and provides an inventory control system to dispense drugs. Kaufmann's device is an inventory control device which dispenses medication to the patient or nurse and is not a physician device nor does it address the physician side of the point-of-care interaction. Kaufman is a device for patient or nursing use: an after- prescription device which does nothing to help the physician select and order an appropriate treatment. Kaufman is not remotely relevant to the prescription management system, or prescription , as claimed in claims 1-71 or the system claimed in claims 80

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With regard to the multi-drug dosage package of claims 72-79, Kaufman does not disclose a package having multiple labeled compartments for each of a number of dosing intervals for multiple drugs, each compartment being intended for and labeled for a single dosage, as now set forth in

amended base independent claim 72. Kaufman stores bulk quantities of drugs in columns 208 inside compartments 202. Desired dosages are dispensed under control of a cpu 22 by a number of delivery mechanisms 206 via a chute 242 to a "medication dispenser" 244 which takes the from of a lockable tray movable between open and closed positions. (col. 1 6, lines I 18). Apparently Kaufman's device delivers loose caplets or pills. It' aufman's device is not remotely a package as claimed by applicants, but is a large machine requiring wheels for mobility. Kauftnan does not provide multiple labeled compartments for each of a number of dosing intervals. Kaufman's compartments 202 presumably have computer addresses to differentiate the drugs they hold, but they are not labeled for dosing intervals. The specific labeling description of claim 73 and the package configuration set forth in claim 74 are plainly quite different from Kaufman. Nor does Kaufman provide an electronically or electro-optically readable scheduled dosage, compartmented pacl<age as required by the device claimed in claim 76. Kaufman is quite unlike and does not remotely suggest applicant's claimed invention.
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New claims. Claim 83 enables a virtual client record which can be assembled on an as-needed basis, consulted bv an authorized user, and then dissolved, without ever having been saved. By uting source data, currency of the data is assured. None of the references suggests a virtual patient record as claimed in claims 83-84 or a system capable of generating treatment recommendations, as required by the method of Claim 85. The Specification. Applicant notes that, owing apparently to a mysterious computer idiosyncracy, the capital letter 'S" has not printed out, in a number of instances throughout the specification. While this is a minor matter causing no significant difficulty in reading the specification, corrected pages will nevertheless be filed at a later date.
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